

Exhibit 7

1 IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

4 IN RE: VALSARTAN, LOSARTAN, MDL No. 2875
AND IRBESARTAN PRODUCTS

5 LIABILITY LITIGATION HON ROBERT B.
KUGLER

7 THIS DOCUMENT APPLIES TO ALL
CASES

8

9

10 - CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

11

12 Remote Videotaped via Zoom

13 Deposition of PENG DONG, commencing at 7:07
14 a.m. Hong Kong time, on the 29th of March,
15 2021, before Maureen O'Connor Pollard,
16 Registered Diplomate Reporter, Realtime
17 Systems Administrator, Certified Shorthand
18 Reporter.

19

20

— — —

21

GOLKOW LITIGATION SERVICES

22

877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

23

24

<p>1 APPEARANCES: ALL PARTIES APPEARED REMOTELY 2 3 FOR THE PLAINTIFFS: 4 5 MAZIE SLATER KATZ & FREEMAN, LLC 6 BY: ADAM SLATER, ESQ. 7 CHERYLL A. CALDERON, ESQ. 8 CHRISTOPHER GEDDIS, ESQ. 9 103 Eisenhower Parkway 10 Roseland, New Jersey 07068 11 973-228-9898 12 aslater@mazieslater.com 13 ccalderon@mazieslater.com 14 cgeddis@mazieslater.com 15 -and- 16 HOLLIS LAW FIRM 17 BY: IRIS SIMPSON, ESQ. 18 8101 College Boulevard, Suite 260 19 Overland Park, Kansas 66210 20 800-701-3672 21 iris@hollislawfirm.com 22 -and- 23 MORGAN & MORGAN 24 BY: STEPHANIE JACKSON, ESQ. 25 20 North Orange Avenue, Suite 1600, 26 Orlando, Florida 32801 27 sjackson@forthepeople.com 28 -and- 29 FLEMING NOLAN JEZ, LLP 30 BY: DAVID HOBBS, ESQ. 31 2800 Post Oak Boulevard 32 Houston, Texas 77056 33 713-621-7944 34 david_hobbs@fleming-law.com 35 36</p>	<p>Page 2 1 APPEARANCES (continued): 2 3 FOR THE DEFENDANT AUROBINDO PHARMACEUTICALS: 4 5 CAITLIN LAWLOR, ESQ. 6 CIPRIANI & WERNER, P.C. 7 450 Sentry Parkway 8 Blue Bell, Pennsylvania 19422 9 610-567-0700 10 clawlor@c-wlaw.com 11 12 FOR THE DEFENDANT MYLAN PHARMACEUTICALS, 13 INC.: 14 FRANK H. STOY, ESQ. 15 PIETRAGALLO GORDON ALFANO BOSICK & 16 RASPANTI, LLP 17 One Oxford Centre 18 Pittsburgh, Pennsylvania 15219 19 412-263-1840 20 fhs@pietragallo.com 21 22 Interpreter: Dr. Yang Shao 23 24 Check Interpreters: Phil Hughes I Ching Ng 25 26 Videographer: Henry Marte 27 28 29 30</p>
<p>1 APPEARANCES (Continued): 2 3 FOR THE PLAINTIFFS: 4 5 FARR LAW FIRM 6 BY: GEORGE T. WILLIAMSON, ESQ. 7 99 Nesbit Street 8 Punta Gorda, Florida 33950 9 941-639-1158 10 gwilliamson@farr.com 11 12 FOR THE DEFENDANTS TEVA PHARMACEUTICAL 13 INDUSTRIES, LTD., TEVA PHARMACEUTICALS SA, 14 INC., ACTAVIS LLC, AND ACTAVIS PHARMA, INC.: 15 KATE M. WITTLAKE, ESQ. 16 GREENBERG TRAURIG LLP 17 4 Embarcadero Center, Suite 3000 18 San Francisco, California 94111 19 415-655-1285 20 wittlakek@gtlaw.com 21 22 FOR THE DEFENDANTS ZHEJIANG HUAHAI 23 PHARMACEUTICAL CO., LTD., PRINSTON 24 PHARMACEUTICAL INC., HUAHAI U.S., INC., and 25 SOLCO HEALTHCARE US, LLC: 26 NATHAN B. REEDER, ESQ. 27 PATRICK C. GALLAGHER, PhD, ESQ. 28 FREDERICK R. BALL, ESQ. 29 DUANE MORRIS, LLP 30 30 South 17th Street 31 Philadelphia, Pennsylvania 19103 32 215-979-1164 33 nbreeder@duanemorris.com 34 pcgallagher@duanemorris.com 35 frball@duanemorris.com 36</p>	<p>Page 3 1 INDEX 2 EXAMINATION 3 PENG DONG 4 BY MR. SLATER 5 6 7 E X H I B I T S 8 NO. DESCRIPTION PAGE 9 ZHP-191 Notice to Take Videotaped 10 Oral Deposition..... 10 11 ZHP-192 Peng Dong's Curriculum Vitae.. 26 12 ZHP-193 Guideline for Genotoxic 13 Impurity Evaluation, Bates 14 ZHP01447235 through 7242..... 33 15 ZHP-194 Change Request Form, Chinese 16 version, Bates ZHP00000161 17 through 214..... 64 18 ZHP-195 Change Request Form, English 19 version, Bates ZHP01843066 20 through 3119..... 64 21 22 23 24</p>

<p>1 DEPOSITION SUPPORT INDEX 2 - - - 3 4 Direction to Witness Not to Answer 5 PAGE LINE 6 None. 7 8 Request for Production of Documents 9 PAGE LINE 10 None. 11 12 Stipulations 13 PAGE LINE 14 None. 15 Questions Marked Highly Confidential 16 PAGE LINE 17 None. 18 19 20 21 22 23 24</p>	<p>Page 6 1 YANG SHAO, Interpreter, 2 having been duly sworn to translate the 3 proceedings to the best of his ability, 4 translated as follows: 5 6 PENG DONG, 7 having been duly affirmed to tell the truth, 8 was examined and testified as follows: 9 EXAMINATION 10 BY MR. SLATER: 11 Q. Hello, Mr. Dong. 12 A. How are you? 13 Q. We're going to take your 14 deposition now. Do you understand that's the 15 purpose of this proceeding? 16 A. I understand. I will attend 17 this deposition as a witness designated by 18 the company. 19 Q. Please make sure that you tell 20 the truth in answering every question. 21 A. I affirm that I will tell the 22 truth. 23 Q. If you are asked a question you 24 don't understand, please tell us, okay?</p>
<p>1 PROCEEDINGS 2 3 THE VIDEOGRAPHER: Okay. We 4 are now on the record. 5 My name is Henry Marte. I'm a 6 videographer on behalf of Golkow 7 Litigation Services. 8 Today's date is March 29, 2021, 9 and the time is 7:07 a.m. 10 This videotaped deposition is 11 being held in the matter of Valsartan, 12 Losartan, and Irbesartan Products 13 Liability Litigation. 14 The deponent today is Mr. Peng 15 Dong. 16 All parties to this deposition 17 are appearing remotely and have agreed 18 to the witness being sworn in 19 remotely. 20 All appearances are also noted 21 on the stenographic record. 22 Will the court reporter please 23 administer the oath to the witness.</p>	<p>Page 7 1 A. All right. 2 Q. All right. If a lawyer objects 3 to a question, please wait, and then you'll 4 likely answer the question, but wait until 5 you're told. 6 A. Okay. 7 Q. Most important, so that we get 8 through this quickly, if I ask you a direct 9 question, for example a yes-or-no question, 10 please answer in a direct way. 11 A. I will tell the truth. 12 Q. Do you, in your -- rephrase. 13 What language or languages do 14 you communicate in at work? 15 A. Mandarin. 16 Q. Do you read or write English at 17 all, whether at work or otherwise? 18 A. I do not write in English. As 19 for the reading, I don't do much English 20 reading. 21 Q. Can you understand English at 22 all? I'm talking spoken. 23 THE VIDEOGRAPHER: Did the 24 witness just freeze? He looks frozen.</p>

<p>1 MR. BALL: He looks frozen. 2 MR. SLATER: Go off. 3 THE VIDEOGRAPHER: All right. 4 The time is 7:13 a.m. Off the record. 5 (Off the record.) 6 THE VIDEOGRAPHER: All right. 7 We are back on the record. The time 8 is 7:15 a.m. 9 BY MR. SLATER: 10 Q. Before we disconnected, I 11 asked, "Do you understand" -- I can't 12 remember if this was answered. Rephrase. 13 Do you understand spoken 14 English at all? 15 A. I would speak very little 16 English, except for the greetings "hello" and 17 "bye-bye." 18 MR. SLATER: Let's mark the 19 deposition notice, whatever exhibit 20 we're up to. 21 (Whereupon, Exhibit Number 22 ZHP-191 was marked for 23 identification.) 24 MR. SLATER: Cheryll, if you</p>	<p>Page 10</p> <p>1 translated when it's not necessary for 2 my questions. 3 MR. BALL: And we could go off 4 the record and talk about this, or you 5 can listen to the objection that I 6 made. 7 MR. SLATER: I heard your 8 objection. He just asked to read the 9 whole document. We're not going down 10 that road. 11 MR. BALL: Mr. Slater, you 12 could have provided a translated 13 document. You chose not to. That's 14 really not my problem that you chose 15 not to. 16 MR. SLATER: All right. Let's 17 continue. 18 BY MR. SLATER: 19 Q. Mr. Peng -- Mr. Dong, were you 20 aware that a deposition notice applies to 21 this deposition? 22 A. I'm not quite sure. 23 Q. Did anybody ever translate the 24 deposition notice for you, to your knowledge,</p>
<p>1 could mark it, put it up on the 2 screen, and then tell us what exhibit 3 number it is, that would be great. 4 MR. BALL: I object to the use 5 of this document without a 6 translation. 7 To the degree that Dr. Shao can 8 translate it for Mr. Peng, I would 9 instruct Mr. Peng to go ahead and 10 answer, or ask Dr. Shao to translate 11 whatever he needs to translate to 12 fully understand the document. 13 THE WITNESS: I need the 14 interpreter to translate the whole 15 document. 16 MR. SLATER: Yeah, we're not 17 going to do that. I'm going to ask my 18 questions, and I'm going to continue. 19 Mr. Ball, if you want to tell 20 him not to answer questions, you can 21 instruct him not to answer. You don't 22 even know what I'm going to ask. 23 But I'm not going to sit here 24 while the whole deposition notice is</p>	<p>Page 11</p> <p>1 and tell you what it said? 2 A. To the best of my recollection, 3 no. 4 Q. Do you know the topics on which 5 you're supposed to be testifying tonight? 6 A. I have some knowledge on those 7 topics. 8 Q. What do you think the topics at 9 this deposition are? 10 A. For that I need to read the 11 original document. 12 Q. If you don't know what the 13 document says, why do you need me to read it 14 to you? 15 MR. BALL: Objection. 16 A. There are several topics where 17 I need to testify on. However, it is 18 impossible for me to recite all those topics 19 one by one. 20 BY MR. SLATER: 21 Q. Recite one for me, please. 22 A. To the best of my recollection, 23 as a corporate witness, I am supposed to 24 testify on the topic of valsartan changes.</p>

<p>1 Q. When you say "valsartan 2 changes," do you mean valsartan process 3 changes?</p> <p>4 MR. BALL: Objection to form.</p> <p>5 A. I would like the opposing 6 counsel to indicate the time frame when you 7 say "valsartan process changes."</p> <p>8 BY MR. SLATER:</p> <p>9 Q. You said you're testifying on 10 valsartan changes. I asked you if you meant 11 valsartan process changes. It's a yes-or-no 12 question.</p> <p>13 MR. BALL: Objection to form.</p> <p>14 A. My understanding regarding 15 valsartan changes might be different from the 16 opposing counsel's understanding of valsartan 17 changes.</p> <p>18 If I am not provided with the 19 real intention and a clear question from the 20 opposing counsel, then it is impossible for 21 me to provide an accurate response to his 22 question.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. When you said that you're here</p>	<p>Page 14</p> <p>1 And, Adam, as you know, that's 2 inappropriate to threaten sanctions. 3 MR. SLATER: I didn't threaten. 4 I said --</p> <p>5 MR. BALL: And if you -- Adam, 6 let me finish, please.</p> <p>7 If you do it again, if you 8 continue to do that, we will consider 9 filing a counter motion if you do.</p> <p>10 You have the document in front 11 of you. You can show him the 12 questions. They can be translated. 13 You chose not to do that. That's 14 really not my problem, again.</p> <p>15 And if you want to go off the 16 record and not take up your time and 17 discuss these issues, I'm happy to do 18 that.</p> <p>19 MR. SLATER: We'll just make a 20 record. It's fine. Let your witness 21 keep answering this way. He's 22 obviously doing it at instruction of 23 counsel, right? I mean, you're in 24 charge, right?</p>
<p>1 to testify on valsartan changes, what did you 2 mean by that?</p> <p>3 A. When I said "valsartan 4 changes," I was referring to the questions 5 that I received or the topics I became aware 6 of that I need to testify as a corporate 7 witness.</p> <p>8 In order to provide an accurate 9 response, either I would be presented with 10 the original document or the interpreter 11 could translate the document for me.</p> <p>12 MR. SLATER: Counsel, I'm just 13 going to ask you to instruct your 14 witness to actually give responsive 15 answers, because this is not 16 responsive. It's canned stuff. And 17 I'm not going to have my time taken by 18 these kinds of answers.</p> <p>19 MR. BALL: Adam, he's giving 20 responsive answers. I'm not going to 21 instruct him to do anything.</p> <p>22 MR. SLATER: I reserve my right 23 to seek sanctions for this time.</p> <p>24 MR. BALL: Fine.</p>	<p>Page 15</p> <p>1 MR. BALL: Objection. Calls 2 for attorney/client privilege.</p> <p>3 MR. SLATER: Okay.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Did you prepare for this 6 deposition?</p> <p>7 A. I did some preparation.</p> <p>8 Q. Who did you prepare for this 9 deposition with?</p> <p>10 A. I reviewed some documents.</p> <p>11 Q. I asked you who you prepared -- 12 rephrase.</p> <p>13 I asked you who you prepared 14 with. What people did you prepare for the 15 deposition with?</p> <p>16 A. I did collect some internal 17 information from my colleagues at ZHP.</p> <p>18 Q. Who?</p> <p>19 A. There are a quite a few. Would 20 you like to know the names of each of them?</p> <p>21 Q. Yes. List the names to the 22 best of your ability, please.</p> <p>23 A. Since I was not involved in any 24 work related to valsartan before 2014, I did</p>

<p>1 approach some people to gather information 2 about valsartan.</p> <p>3 Q. I asked you to list the names 4 of the people. Can you just list the names 5 for me, please?</p> <p>6 A. What do you mean by listing 7 their names? Do you want me to orally 8 repeat?</p> <p>9 Q. Yes. I would like you to tell 10 me their names. This is a sworn oral 11 deposition, so please speak the names.</p> <p>12 MR. BALL: Objection. 13 Harassment.</p> <p>14 MR. SLATER: Harassment because 15 I -- wait a second. Harassment? He 16 said, "Would you like me to list the 17 names" three questions ago. I said 18 "Yes," and now he's acting like he 19 doesn't understand what I'm asking.</p> <p>20 Counsel, it's like five or six 21 times he's done this already. It's 22 outrageous.</p> <p>23 MR. BALL: Please go off the 24 record for a second.</p>	<p>Page 18</p> <p>1 Q. Did you speak to any lawyers to 2 prepare for the deposition?</p> <p>3 A. I did talk with attorneys in 4 the past.</p> <p>5 Q. To prepare for this deposition?</p> <p>6 A. We did have some conversation.</p> <p>7 Q. Which lawyers did you speak to?</p> <p>8 A. For example, this attorney from 9 our side.</p> <p>10 Q. Mr. Dong, can you tell me the 11 name of each lawyer that helped prepare you 12 for this deposition, please?</p> <p>13 A. I did have some conversation 14 with the attorneys.</p> <p>15 Q. What are their names?</p> <p>16 A. My English skill is poor, so if 17 I pronounce correctly, I believe his name is 18 Rick.</p> <p>19 Q. Who else?</p> <p>20 A. I'm afraid I cannot pronounce 21 the name of that person.</p> <p>22 Q. Tell me the name of any Chinese 23 lawyers who helped to prepare you for the 24 deposition, please.</p>
<p>Page 19</p> <p>1 THE VIDEOGRAPHER: All right. 2 The time is 7:32 a.m. Off the record.</p> <p>3 (Off the record discussion.)</p> <p>4 THE VIDEOGRAPHER: The time is 5 7:34 a.m. Back on the record.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Please tell me the name of each 8 person you spoke with to prepare for this 9 deposition.</p> <p>10 A. Every name? There are many 11 names. I'm afraid I cannot recall each and 12 every name.</p> <p>13 Q. List the ones you can recall, 14 please, speaking them to me, please.</p> <p>15 A. Let me see.</p> <p>16 THE INTERPRETER: The 17 interpreter would like to clarify with 18 the witness.</p> <p>19 A. For example, Yueling Hu, 20 spelled as Y-U-E-L-I-N-G, last name H-U.</p> <p>21 Q. That's the only name you can 22 remember?</p> <p>23 A. That's all I can recall as of 24 now.</p>	<p>Page 20</p> <p>1 MR. BALL: Objection to form.</p> <p>2 A. What do you mean by any Chinese 3 attorneys?</p> <p>4 BY MR. SLATER:</p> <p>5 Q. An attorney from China whose 6 name you can remember.</p> <p>7 A. To the best of my recollection, 8 I never had a conversation with so-called 9 Chinese attorneys.</p> <p>10 Q. So is the attorney who you 11 said, Rick, the lawyer who is on this 12 deposition with us, Mr. Rick Ball?</p> <p>13 A. That is correct.</p> <p>14 Q. How many times did you speak to 15 him to prepare for the deposition?</p> <p>16 A. We did talk to each other for a 17 few times. However, I do not recall the 18 exact time, or times.</p> <p>19 Q. For how long did you speak to 20 Mr. Ball preparing for the deposition?</p> <p>21 A. What do you mean by -- how long 22 is the conversation?</p> <p>23 Q. How much time did you speak to 24 him for over the course of your discussions</p>

<p>1 with him preparing for the deposition?</p> <p>2 MR. BALL: Objection to form.</p> <p>3 A. I did have some discussion with</p> <p>4 him. However, I would like some</p> <p>5 clarification from the plaintiffs' attorney.</p> <p>6 Do you mean the total length of</p> <p>7 time for the discussion between us?</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Yes.</p> <p>10 A. I don't recall.</p> <p>11 Q. Was it more than an hour?</p> <p>12 A. My conversation with that</p> <p>13 attorney took more than an hour.</p> <p>14 Q. More than five hours?</p> <p>15 A. Well, maybe.</p> <p>16 Q. Did you bring any documents to</p> <p>17 give to me as part of this deposition?</p> <p>18 A. I don't understand your</p> <p>19 question. What do you mean by bringing any</p> <p>20 document to you?</p> <p>21 Q. Are you producing any documents</p> <p>22 in connection with the deposition?</p> <p>23 MR. BALL: Objection. Vague.</p> <p>24 A. I don't understand what you</p>	<p>Page 22</p> <p>1 To the best of my recollection,</p> <p>2 at that time I was at a very junior level,</p> <p>3 and I was not authorized to apply for an</p> <p>4 e-mail address.</p> <p>5 Q. Are you saying you didn't use</p> <p>6 e-mail when you first started working at ZHP?</p> <p>7 A. That is correct.</p> <p>8 Q. When did you first get e-mail</p> <p>9 at your company?</p> <p>10 Let me ask it differently.</p> <p>11 Withdrawn. New question.</p> <p>12 When did you first have an</p> <p>13 e-mail address at your work at ZHP?</p> <p>14 A. I believe it was a long time</p> <p>15 ago that I started to have my work e-mail at</p> <p>16 ZHP. I do not recall.</p> <p>17 Q. Did you have e-mail at ZHP</p> <p>18 before December 12, 2017?</p> <p>19 A. Yes.</p> <p>20 Q. Did you send and receive</p> <p>21 e-mails before December 12, 2017 in your work</p> <p>22 at ZHP?</p> <p>23 A. From that date or since that</p> <p>24 date, I have been receiving and sending</p>
<p>1 mean.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Okay. Do you know what a</p> <p>4 document is?</p> <p>5 A. There are many types of</p> <p>6 documents.</p> <p>7 Q. Great. Are you producing any</p> <p>8 types of documents as part of this</p> <p>9 deposition? Are you bringing anything --</p> <p>10 rephrase.</p> <p>11 Are there any documents that</p> <p>12 you're producing as part of this deposition,</p> <p>13 any type?</p> <p>14 MR. BALL: Objection to form.</p> <p>15 A. I don't understand the word</p> <p>16 "producing."</p> <p>17 BY MR. SLATER:</p> <p>18 Q. At your work, do you</p> <p>19 communicate with your coworkers by e-mail?</p> <p>20 A. Yes.</p> <p>21 Q. Has that been true since you</p> <p>22 first started to work for ZHP?</p> <p>23 A. Let me see. It has been a long</p> <p>24 time between now and my first day at ZHP.</p>	<p>Page 23</p> <p>1 e-mails using my work e-mail address in the</p> <p>2 course of my employment.</p> <p>3 Q. I asked if you did so before</p> <p>4 December 12, 2017. Please answer that</p> <p>5 question.</p> <p>6 A. Yes.</p> <p>7 Q. Do you know when you first sent</p> <p>8 or received e-mails in your work at ZHP?</p> <p>9 A. I don't recall, since it was</p> <p>10 long time ago.</p> <p>11 MR. SLATER: Cheryll, I want to</p> <p>12 put up the CV only if it was produced</p> <p>13 by ZHP to us. So can you tell me, was</p> <p>14 it produced by ZHP, or did we get it</p> <p>15 from somewhere else? Did we get it</p> <p>16 from them, or did we get it from</p> <p>17 somewhere else?</p> <p>18 I'm asking my associate. It's</p> <p>19 not a question.</p> <p>20 MS. CALDERON: We received the</p> <p>21 CV from counsel.</p> <p>22 MR. SLATER: Great. Put it on</p> <p>23 the screen. Next exhibit, 192.</p> <p>24 ///</p>

<p>1 (Whereupon, Exhibit Number 2 ZHP-192 was marked for 3 identification.)</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Mr. Dong, in front of us is the 6 CV -- rephrase.</p> <p>7 Mr. Dong, you can't read the 8 document in front of you, right?</p> <p>9 A. Well, I am only familiar with a 10 few words in this document.</p> <p>11 MR. SLATER: For the record, 12 this document was produced to us by 13 counsel as Mr. Dong's CV. Just making 14 that record.</p> <p>15 Q. Mr. Dong, do you have a CV in 16 the Chinese or Mandarin language that you'd 17 be able to read completely?</p> <p>18 A. To the best of my recollection, 19 I do not have my CV in Chinese. And this 20 version was actually written by a colleague 21 of mine when I told him the content.</p> <p>22 Q. Do you know whether it's 23 accurate or not?</p> <p>24 A. What do you mean by this</p>	<p>Page 26</p> <p>1 technical department at Chuannan facility of 2 ZHP.</p> <p>3 Q. What is the responsibility of 4 the technical department?</p> <p>5 A. Are you referring to the 6 responsibilities of my position or the whole 7 department when you said "the responsibility 8 of the technical department"?</p> <p>9 Q. When I said -- rephrase.</p> <p>10 The technical department.</p> <p>11 That's why I asked the question that way.</p> <p>12 Hold on. Hold on.</p> <p>13 The technical department, the 14 whole department.</p> <p>15 A. The responsibility of the 16 technical department covers two areas. One 17 is management of technology, or technical 18 management. The other area is improvement of 19 the process or processes.</p> <p>20 Q. What processes are you 21 referring to?</p> <p>22 A. I did not say "processes," so I 23 don't understand the question.</p> <p>24 Q. That was the translation I was</p>
<p>1 document accurate or not?</p> <p>2 Q. Is the information correct?</p> <p>3 A. Which specific entry are you 4 referring to?</p> <p>5 Q. The whole thing.</p> <p>6 MR. BALL: Again, I'm going to 7 object to the use of this document.</p> <p>8 If you want to translate 9 certain sections and have Dr. Shao 10 translate sections of it, he can 11 answer questions about it. Just what 12 he just told you, Adam.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. I'm waiting for an answer.</p> <p>15 A. Excuse me. What was the 16 original question of the plaintiffs' 17 attorney?</p> <p>18 Q. What department do you work in?</p> <p>19 MR. BALL: Object to form.</p> <p>20 A. When you say do I work, do you 21 mean my current job position?</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Yes.</p> <p>24 A. Right now I work in the</p>	<p>Page 27</p> <p>1 given. You said "process or processes," 2 so...</p> <p>3 THE INTERPRETER: The 4 interpreter clarifies that in Chinese 5 there is no singular or plural form. 6 So, to be complete, the interpreter 7 choose to use both the singular or the 8 plural form, just in case.</p> <p>9 Q. Okay. I'll ask a new question.</p> <p>10 What process are you referring 11 to?</p> <p>12 A. The responsibility of the 13 technical department is to improve and 14 upgrade the manufacturing process for the 15 products under our management.</p> <p>16 MR. BALL: Please don't 17 translate this.</p> <p>18 Adam, are you asking him in his 19 capacity as a 30(b)(6) witness? His 20 individual capacity?</p> <p>21 Can I finish, please? I 22 thought the deposition started with 23 the 30(b)(6) questions.</p> <p>24 MR. SLATER: I think I'm</p>

<p>1 allowed to find out who the witness is 2 and what department he works in as 3 part of the 30(b)(6).</p> <p>4 MR. BALL: I just want to make 5 sure that these -- then I'm going to 6 object.</p> <p>7 And I'm just going to put on 8 the record these answers, I believe, 9 are outside the scope of the 30(b)(6) 10 and don't bind the company.</p> <p>11 Go ahead.</p> <p>12 MR. SLATER: I'm sorry. You 13 think that me asking the 30(b)(6) 14 witness what his department does is 15 outside the scope of the deposition?</p> <p>16 MR. BALL: Yes, I do believe 17 that. Outside the scope of the 18 30(b)(6). You can ask him in his 19 individual capacity, and that's fine. 20 He's not binding the company.</p> <p>21 MR. SLATER: That's great. We 22 disagree.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. What are your responsibilities</p>	<p>Page 30</p> <p>1 A. In Chinese, literally it's 2 translated as director assistant.</p> <p>3 MR. SLATER: I'm going to go 4 into a new area now. I don't know 5 when you need your first break. I 6 know that you need breaks 7 periodically, so I just...</p> <p>8 THE INTERPRETER: The 9 interpreter would request a brief 10 break in order to start the realtime.</p> <p>11 MR. SLATER: Great. Let's go 12 off.</p> <p>13 MR. BALL: Okay. Hold on, hold 14 on.</p> <p>15 Dong, do you have -- is your 16 breakfast there? Do we need to take 17 15 minutes, or are we just going to 18 take 10?</p> <p>19 MR. SLATER: Go off the video. 20 We're not using my time to get his 21 breakfast menu, please.</p> <p>22 THE VIDEOGRAPHER: All right. 23 The time is 8:08 a.m. Going off the 24 record.</p> <p>Page 31</p> <p>1 in your position?</p> <p>2 A. My own responsibilities would 3 cover three areas.</p> <p>4 First, management of the 5 department. Second, to organize my 6 subsidiaries to conduct technical management. 7 The third one, participation in organization 8 of the improvement of manufacturing process 9 for the product we manage.</p> <p>10 Q. Your current title is deputy 11 director of the technical department, is that 12 correct?</p> <p>13 A. That is correct.</p> <p>14 Q. When did you get that title?</p> <p>15 What day?</p> <p>16 A. I do not recall the specific 17 month and day.</p> <p>18 Q. Tell me what you do recall.</p> <p>19 A. To the best of my recollection, 20 I was promoted to that title in early 2018, 21 but I do not recall the specific month and 22 date.</p> <p>23 Q. Your prior title was assistant 24 director, correct?</p>
<p>1 in your position?</p> <p>2 A. My own responsibilities would 3 cover three areas.</p> <p>4 First, management of the 5 department. Second, to organize my 6 subsidiaries to conduct technical management. 7 The third one, participation in organization 8 of the improvement of manufacturing process 9 for the product we manage.</p> <p>10 Q. Your current title is deputy 11 director of the technical department, is that 12 correct?</p> <p>13 A. That is correct.</p> <p>14 Q. When did you get that title?</p> <p>15 What day?</p> <p>16 A. I do not recall the specific 17 month and day.</p> <p>18 Q. Tell me what you do recall.</p> <p>19 A. To the best of my recollection, 20 I was promoted to that title in early 2018, 21 but I do not recall the specific month and 22 date.</p> <p>23 Q. Your prior title was assistant 24 director, correct?</p>	<p>Page 32</p> <p>1 A. In Chinese, literally it's 2 translated as director assistant.</p> <p>3 MR. SLATER: I'm going to go 4 into a new area now. I don't know 5 when you need your first break. I 6 know that you need breaks 7 periodically, so I just...</p> <p>8 THE INTERPRETER: The 9 interpreter would request a brief 10 break in order to start the realtime.</p> <p>11 MR. SLATER: Great. Let's go 12 off.</p> <p>13 MR. BALL: Okay. Hold on, hold 14 on.</p> <p>15 Dong, do you have -- is your 16 breakfast there? Do we need to take 17 15 minutes, or are we just going to 18 take 10?</p> <p>19 MR. SLATER: Go off the video. 20 We're not using my time to get his 21 breakfast menu, please.</p> <p>22 THE VIDEOGRAPHER: All right. 23 The time is 8:08 a.m. Going off the 24 record.</p> <p>Page 33</p> <p>1 (Whereupon, a recess was 2 taken.)</p> <p>3 THE VIDEOGRAPHER: The time is 4 8:24 a.m. Back on the record.</p> <p>5 (Whereupon, Exhibit Number 6 ZHP-193 was marked for 7 identification.)</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Do you see this exhibit in 10 front of you titled "Guideline for Genotoxic 11 Impurity Evaluation"?</p> <p>12 A. I see it.</p> <p>13 Q. Look at Section 2, please.</p> <p>14 This states in part, "All intermediates and 15 APIs produced under GMP conditions must be 16 identified for genotoxic impurities."</p> <p>17 Do you see that?</p> <p>18 A. I see it. The document does 19 state so.</p> <p>20 Q. Identification of genotoxic 21 impurities is part of the risk assessment 22 evaluation, correct?</p> <p>23 A. Per the requirements of ICH, we 24 would confirm the quality specifications of</p>

<p>1 API.</p> <p>2 Q. This applies to valsartan,</p> <p>3 correct?</p> <p>4 Let me reask the question.</p> <p>5 Hang on. Let me reask the question.</p> <p>6 What you just stated would</p> <p>7 apply to valsartan, correct?</p> <p>8 A. For API products, including</p> <p>9 valsartan API, we would confirm the quality</p> <p>10 specifications per the requirements of ICH.</p> <p>11 Q. Part of evaluating -- rephrase.</p> <p>12 Part of this process includes</p> <p>13 identifying all genotoxic impurities,</p> <p>14 correct?</p> <p>15 A. What do you mean by "part of</p> <p>16 this process"?</p> <p>17 Q. The GMP process to ensure the</p> <p>18 product meets quality requirements.</p> <p>19 A. Can you repeat your question by</p> <p>20 putting what you just said? I'm sorry.</p> <p>21 Q. No.</p> <p>22 Let's go to Section 4.2.1. In</p> <p>23 part, this says, "Sources of genotoxic</p> <p>24 substances include raw materials, reagents,</p>	<p>Page 34</p> <p>1 As for those ICH requirements</p> <p>2 and SOPs, they had certain effective period</p> <p>3 of time, and that would start with an</p> <p>4 effective date.</p> <p>5 MR. SLATER: Move to strike.</p> <p>6 Q. It's a very simple question.</p> <p>7 The information I read to you in</p> <p>8 Section 4.2.1, did ZHP know the sources of</p> <p>9 the genotoxic substances when it first</p> <p>10 started manufacturing valsartan? Yes or no.</p> <p>11 Did it know that list or not?</p> <p>12 A. Section 4.2.1 is indeed</p> <p>13 included in this document. However, I need</p> <p>14 to know the effective date of this document.</p> <p>15 In addition, we conducted our</p> <p>16 work in developing the manufacturing process</p> <p>17 of valsartan based on the requirements of ICH</p> <p>18 then, as well as the internal SOP regulations</p> <p>19 then.</p> <p>20 MR. SLATER: Move to strike.</p> <p>21 Q. I'm going to ask you a question</p> <p>22 not referring to this document to try to get</p> <p>23 you to answer responsively.</p> <p>24 From the time ZHP began to</p> <p>Page 35</p>	<p>Page 36</p>
<p>1 solvents, intermediates, and by-products,"</p> <p>2 correct?</p> <p>3 A. The document does say so in</p> <p>4 Chinese.</p> <p>5 Q. And your company knew that from</p> <p>6 the time it began to manufacture valsartan,</p> <p>7 correct?</p> <p>8 A. I believe this document should</p> <p>9 have an effective date. I'm sorry, I missed</p> <p>10 the effective date.</p> <p>11 Q. My question --</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 Q. What I just read in 4.2.1 your</p> <p>14 company has known from the first day it ever</p> <p>15 manufactured valsartan, correct?</p> <p>16 A. I need to know the effective</p> <p>17 date of this document.</p> <p>18 Q. Do you know if your company</p> <p>19 knew the sources of genotoxic substances when</p> <p>20 it first started manufacturing valsartan?</p> <p>21 Yes or no.</p> <p>22 A. We conducted our work based on</p> <p>23 the requirements of ICH as well as the</p> <p>24 regulations of our internal SOPs.</p>	<p>1 manufacture valsartan, did it know that the</p> <p>2 sources of genotoxic substances included raw</p> <p>3 materials, reagents, solvents, intermediates,</p> <p>4 and by-products? Yes or no.</p> <p>5 A. When ZHP first started to</p> <p>6 manufacture valsartan, they conducted the</p> <p>7 work based on the requirement of ICH then, as</p> <p>8 well as the regulations of the internal SOP</p> <p>9 then.</p> <p>10 When I mentioned ICH and SOP, I</p> <p>11 was referring to the documents then.</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 Q. Can you just answer with a yes</p> <p>14 or no, please, the actual question I asked?</p> <p>15 A. What was your original question</p> <p>16 again?</p> <p>17 MR. SLATER: Go off the record.</p> <p>18 THE VIDEOGRAPHER: All right.</p> <p>19 The time is 8:40 a.m. Off the record.</p> <p>20 (Off the record discussion.)</p> <p>21 THE VIDEOGRAPHER: The time is</p> <p>22 8:41 a.m. Back on the record.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. I am told that this document</p>	<p>Page 37</p>

<p>1 was created in 2011.</p> <p>2 MR. BALL: Objection to form.</p> <p>3 MR. SLATER: What's the</p> <p>4 objection?</p> <p>5 MR. BALL: Foundation. You</p> <p>6 were told, Adam?</p> <p>7 MR. SLATER: You're really</p> <p>8 having a fun time over there, Rick,</p> <p>9 aren't you?</p> <p>10 MR. BALL: You know, Adam, I'm</p> <p>11 going to make my objections. You</p> <p>12 asked me what my objection was, and I</p> <p>13 just told you.</p> <p>14 MR. SLATER: I hadn't even</p> <p>15 finished my sentence, but --</p> <p>16 MR. BALL: Okay.</p> <p>17 MR. SLATER: -- keep having a</p> <p>18 grand time over there. It's fine.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. I'm told that the metadata for</p> <p>21 this document shows that it was created in</p> <p>22 2011. Do you know whether that's correct or</p> <p>23 not?</p> <p>24 MR. BALL: Objection to form.</p>	<p>Page 38</p> <p>1 document before, what time frame are you</p> <p>2 referring to?</p> <p>3 Q. Ever in your life before today.</p> <p>4 A. To the best of my recollection,</p> <p>5 I have seen this document before. It seems</p> <p>6 so.</p> <p>7 Q. Have you ever used this</p> <p>8 document in your work?</p> <p>9 A. In the course of my employment,</p> <p>10 we conducted our work based on the</p> <p>11 requirements of ICH and SOP then.</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 MR. BALL: Oppose the motion.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Mr. Dong, did I ask you about</p> <p>16 ICH? No, I didn't.</p> <p>17 Did I ask you about any other</p> <p>18 SOPs? No, I didn't.</p> <p>19 I would appreciate, like I</p> <p>20 asked you up front, to be courteous and</p> <p>21 comply with your obligations under the United</p> <p>22 States Federal Rules of Civil Procedure and</p> <p>23 answer the questions I actually ask you. I</p> <p>24 would really appreciate that. It would make</p>
<p>1 A. Can you show me the time? I</p> <p>2 cannot find that time in this document.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. I asked you if you know.</p> <p>5 Either the answer is yes or no.</p> <p>6 MR. BALL: Objection to form.</p> <p>7 A. Judging from what is shown to</p> <p>8 me on the screen, it is impossible for me to</p> <p>9 tell when this document was created, nor</p> <p>10 could I tell that -- what the effective date</p> <p>11 of this document is.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Have you ever seen this</p> <p>14 document --</p> <p>15 MR. SLATER: Move to strike.</p> <p>16 Q. Have you ever seen this</p> <p>17 document --</p> <p>18 MR. BALL: Oppose the motion.</p> <p>19 MR. SLATER: I'm going to start</p> <p>20 over.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Have you ever seen this</p> <p>23 document before?</p> <p>24 A. When you said have I seen this</p>	<p>Page 39</p> <p>1 things go a lot smoother for everybody.</p> <p>2 MR. BALL: Objection to form.</p> <p>3 I don't even know if that was a</p> <p>4 question.</p> <p>5 MR. SLATER: No. It was a</p> <p>6 request for the witness to actually</p> <p>7 make some minimal effort to be</p> <p>8 responsive.</p> <p>9 MR. BALL: Objection.</p> <p>10 Harassment.</p> <p>11 Go ahead and translate it.</p> <p>12 A. I will tell you the truth.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Look at Section 4.2.3. It says</p> <p>15 in part, "After product pilot, genotoxic</p> <p>16 impurities should be preliminarily determined</p> <p>17 and included in the development report."</p> <p>18 Correct?</p> <p>19 MR. BALL: Objection to form.</p> <p>20 A. According to this document, it</p> <p>21 says in this section, "After the research and</p> <p>22 development of the product pilot, genotoxic</p> <p>23 impurities should be preliminarily determined</p> <p>24 and included in the development report."</p>

<p>1 That's what it says in Chinese. 2 BY MR. SLATER: 3 Q. Look at 4.2.4. That says, "The 4 identification of genotoxic impurities should 5 include confirmed structure of genotoxic 6 impurities and confirm analysis method and 7 residual limit of the impurity." Correct? 8 MR. BALL: Objection to form. 9 A. According to this document, the 10 Chinese statement does say so in 11 Section 4.2.4. 12 BY MR. SLATER: 13 Q. Let's go to Section 4.3.1. 14 This section says, "The technical department 15 organizes relevant departments to evaluate 16 all raw materials, reagents, solvents, 17 intermediates, and by-products of the product 18 and evaluate whether they contain genotoxic 19 substances." Correct? 20 MR. BALL: Objection to form. 21 A. In Section 4.3.1 of this 22 document, the Chinese version says, "The 23 technical department should organize relevant 24 departments to evaluate all raw materials,</p>	<p>Page 42</p> <p>1 your technical department, the one you work 2 in, correct? 3 MR. BALL: Objection to form. 4 BY MR. SLATER: 5 Q. Let me stop. Let me stop. Let 6 me withdraw the question. 7 There's a technical department 8 for the Chuannan facility where the valsartan 9 API was manufactured, correct? 10 MR. BALL: Objection to form. 11 A. There is a technical department 12 at the Chuannan facility of ZHP. 13 BY MR. SLATER: 14 Q. This guideline applies to that 15 technical department, correct? 16 MR. BALL: Objection to form. 17 A. Are you referring to this SOP 18 by "this guideline"?</p> <p>19 BY MR. SLATER: 20 Q. Yes. 21 A. Can you repeat the pending 22 question? I'm sorry. 23 Q. This guideline that is on the 24 screen applies to the technical department in</p>
<p>Page 43</p> <p>1 reagents, solvents, intermediates, and 2 by-products of the product, and evaluate 3 whether there are any genotoxic substances in 4 them." That's what the Chinese says. 5 BY MR. SLATER: 6 Q. The technical department is the 7 department that you work in, correct? 8 MR. BALL: Objection to form. 9 A. Do you mean the technical 10 department described in this document when 11 you say "technical department"?</p> <p>12 BY MR. SLATER: 13 Q. Is the technical department 14 referenced in 4.3.1 the department you work 15 in? 16 MR. BALL: Objection to form. 17 A. The technical departments 18 referred in this document under Section 4.3.1 19 refer to all the technical departments in 20 ZHP's facilities. My department is only one 21 of them. 22 BY MR. SLATER: 23 Q. This instruction to the 24 technical departments would also apply to</p>	<p>Page 45</p> <p>1 Chuannan, correct? 2 MR. BALL: Objection -- sorry. 3 Objection to form. 4 A. The technical department in 5 Chuannan should conduct their work based on 6 the current SOP. 7 BY MR. SLATER: 8 Q. When Section 4.3.1 refers to 9 the "technical departments" plural, that 10 includes the technical department at 11 Chuannan, correct? 12 MR. BALL: Objection to form. 13 A. After this SOP became 14 effective, all the technical departments 15 referred to under Section 4.1 point -- 16 THE INTERPRETER: The 17 interpreter's correction. 18 A. -- under Section 4.3.1, 19 including the technical department in 20 Chuannan, need to conduct their work based on 21 the effective SOP at that time. 22 BY MR. SLATER: 23 Q. Look at 4.4.1. The first part 24 says, "Genotoxic substances are potentially</p>

<p>1 destructive to DNA at any intake level, and 2 this damage may lead to tumors." Correct? 3 It says that in part, correct? 4 MR. BALL: Objection to form. 5 A. One sentence under 6 Section 4.4.1 of this document does say that 7 "Genotoxic substances are potentially 8 destructive to DNA at any intake level, and 9 this damage may lead to tumors." 10 This sentence is only within 11 this paragraph under Section 4.4.1. 12 BY MR. SLATER: 13 Q. Go to Section 4.4.11. This 14 indicates that "Genotoxic impurities and 15 their residual limits as found by the company 16 are found in Appendix A." Correct? 17 MR. BALL: Objection to form. 18 A. In this document under 19 Section 4.4.11, the sentence in Chinese does 20 say, "The genotoxic impurities and their 21 residual limits as determined by the company 22 are found in Appendix A." 23 In addition, could you please 24 scroll up this document a little bit? It</p>	<p>Page 46</p> <p>1 your question. Are you asking me whether I'm 2 done with responding to the previous 3 question? 4 BY MR. SLATER: 5 Q. Because it says "002," that 6 means it's the second version. You know how 7 your documents are written in your company, 8 right? 9 MR. BALL: Objection to form. 10 Harassment. 11 A. I need to review the whole 12 document before responding to the opposing 13 counsel's question. 14 BY MR. SLATER: 15 Q. We can go off the record if you 16 want to read the whole document. 17 MR. BALL: No, we won't. He 18 can read it on the record. He will 19 take the time, your time, to do that. 20 MR. SLATER: I'm sorry, but 21 we're not going to. I'm not going to 22 sit while he reads the whole document. 23 I don't know what he's reading for. 24 The date of the document is not on it,</p>
<p>1 makes me feel tired when I have to look down 2 at this paragraph. I'm sorry. 3 MR. SLATER: I don't 4 understand. Move to strike the last 5 part. 6 MR. BALL: Oppose the motion. 7 BY MR. SLATER: 8 Q. Mr. Dong, if you look in the 9 top left, it says number "API-R&D-002." 10 Do you see that? 11 MR. BALL: Objection to form. 12 A. As shown on the screen, on this 13 document at the upper left corner, there is 14 indeed a number "API-R&D-002." 15 BY MR. SLATER: 16 Q. By -- rephrase. 17 Since it says "002," this is 18 version 2 of this guideline, correct? 19 MR. BALL: Objection to form. 20 A. This is a document number. 21 BY MR. SLATER: 22 Q. That's your answer? 23 MR. BALL: Objection to form. 24 A. I'm sorry. I don't understand</p>	<p>Page 47</p> <p>1 so I don't know what he's looking for. 2 MR. BALL: Well, then, I don't 3 know what he's looking for either. 4 Why don't you ask him. But we're not 5 going off the record. 6 MR. SLATER: This isn't how 7 we're going to do this. 8 MR. BALL: We're not going off 9 the record. 10 MR. SLATER: I've got a 11 different way of asking it, Mr. Ball. 12 BY MR. SLATER: 13 Q. Mr. Dong, do you know if this 14 is the only version of this document or not? 15 Yes or no. It's a simple yes-or-no question. 16 MR. BALL: Objection to form. 17 A. In order to provide an accurate 18 answer, I need to review the whole document. 19 BY MR. SLATER: 20 Q. Okay. Well, you can do that on 21 your own time. 22 MR. SLATER: Let's go to 23 Appendix A. Perfect. 24 Q. This is Appendix A, correct?</p>

<p>1 MR. BALL: Objection to form. 2 A. It says here after "Attachment 3 A," "List of genotoxic impurities by ZHP." 4 That's what it says. 5 BY MR. SLATER: 6 Q. In line 7, line 9, and line 10, 7 the product in the right-hand column is 8 valsartan, correct? 9 MR. BALL: Objection to form. 10 A. In line 7, line 9, and line 10 11 of this document, in the right-hand column, 12 the product in Chinese is valsartan. 13 BY MR. SLATER: 14 Q. The left-hand column is the 15 list of impurities. 16 Do you see that? 17 MR. BALL: Objection to form. 18 MR. SLATER: What's your 19 objection, Counsel? 20 MR. BALL: My objection is, why 21 don't you -- never mind. I don't -- 22 my objection is that's vague, first 23 off. 24 MR. SLATER: Are you just</p>	<p>Page 50</p> <p>1 was "The left-hand column 2 says...correct?" Which is you 3 translating the left-hand column and 4 asking my witness if that's what it 5 says. 6 MR. SLATER: Yes. Right. And 7 then if it's -- and then -- all right. 8 And then if he's -- all right. 9 Whatever. You know what? Nice. 10 Good. 11 BY MR. SLATER: 12 Q. The left-hand column, the title 13 is "List of impurities," correct? 14 MR. BALL: Objection to form. 15 A. In this list, the second column 16 at the top says in Chinese "Names of the 17 impurities of genotoxicity." That's what it 18 says in Chinese. 19 BY MR. SLATER: 20 Q. Next to number 7 in that 21 column, it says "azide," correct? 22 MR. BALL: Objection to form. 23 BY MR. SLATER: 24 Q. I'll ask it differently.</p>
<p>1 objecting to form to -- 2 MR. BALL: You haven't laid a 3 foundation. You haven't laid a 4 foundation. 5 MR. SLATER: Okay. I think 6 you're objecting to form every time 7 you can't read the language, just 8 to -- just for the heck of it. I 9 mean -- 10 MR. BALL: As far as I know, 11 Adam, you don't read Chinese. 12 MR. SLATER: No, I don't. 13 MR. BALL: So I'm not relying 14 on your translation of it. 15 MR. SLATER: Okay. So you're 16 objecting to the form in case the 17 translation is wrong? 18 MR. BALL: I'm objecting to 19 the -- I'm objecting that you did not 20 lay a foundation for what the 21 left-hand column says. 22 MR. SLATER: Okay. That's what 23 that question was, actually. 24 MR. BALL: No, it wasn't. It</p>	<p>Page 51</p> <p>1 How about we'll do it this way. 2 On line 7 in the impurities column that you 3 just read the title for, what is the impurity 4 that's listed there? 5 A. In this table under the second 6 column in line 7, it says "azide" here. 7 Q. What does it say in line 9 in 8 that column for valsartan? 9 A. What do you mean by "line 9 in 10 that column for valsartan"? Are you asking 11 me to read aloud the content of the whole 12 line 9? 13 Q. In the column that's titled 14 "Names of the impurities," next to the number 15 9, what does it say for the impurity? 16 A. In the table as shown on the 17 screen, under column 2 in line 9, it says 18 "Bromo OBTN." 19 Q. What does it say directly 20 beneath that on line 10 in that column? 21 A. In the table shown on the 22 screen, under column 2 in line 10, it says 23 "Bromo OBTN tetrazole." 24 Q. Let's go to the prior page.</p>

<p style="text-align: right;">Page 54</p> <p>1 Looking at the top of this 2 page, does this tell you whether this is the 3 first version of this guideline or not? 4 A. According to what's shown on 5 the screen, it says here in Chinese, "This 6 document is a new document." Based on that, 7 I can determine that this document is a first 8 version.</p> <p>9 MR. BALL: I didn't hear what 10 you said. You "can determine" or you 11 "can't determine"?</p> <p>12 I'm asking the translator what 13 he said.</p> <p>14 THE INTERPRETER: The 15 interpreter would repeat.</p> <p>16 A. I can, C-A-N, determine this is 17 a first version.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. To your recollection, has -- 20 we'll rephrase.</p> <p>21 When the process change 22 occurred to include zinc chloride in the 23 process, was this guideline applied by ZHP?</p> <p>24 A. I'm sorry. Since I did not see</p>	<p style="text-align: right;">Page 56</p> <p>1 BY MR. SLATER: 2 Q. Is the answer -- 3 MR. BALL: Oppose the motion. 4 MR. SLATER: I'm just saying it 5 because you talked over me.</p> <p>6 BY MR. SLATER: 7 Q. Is the answer yes or no? 8 Please answer.</p> <p>9 MR. BALL: Objection to form. 10 A. Could you repeat the question?</p> <p>11 BY MR. SLATER: 12 Q. How did I know you were going 13 to ask me that? I'll try it for the third 14 time.</p> <p>15 Was this guideline applied and 16 used when the process change to the zinc 17 chloride process for valsartan was made?</p> <p>18 MR. BALL: Objection to form. 19 BY MR. SLATER: 20 Q. Yes or no.</p> <p>21 MR. BALL: Objection to form. 22 A. During the process change for 23 valsartan, we conducted corresponding work 24 based on the requirements of ICH then, as</p>
<p style="text-align: right;">Page 55</p> <p>1 the effective date of this document, I cannot 2 provide an accurate response to your 3 question.</p> <p>4 Q. I can scroll -- rephrase.</p> <p>5 There is no effective date on 6 the document. Not written on it.</p> <p>7 MR. BALL: Objection to form.</p> <p>8 I don't know if there's a question.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. Here's the question. You -- 11 we'll rephrase.</p> <p>12 Was this guideline applied to 13 the zinc chloride process change for 14 valsartan? Yes or no.</p> <p>15 MR. BALL: Objection to form.</p> <p>16 A. During the process change for 17 valsartan, we conducted our work based on the 18 ICH and SOP requirements at that time.</p> <p>19 MR. SLATER: Move to strike.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Is the answer yes?</p> <p>22 MR. BALL: Oppose the motion.</p> <p>23 MR. SLATER: Move to strike.</p> <p>24 ///</p>	<p style="text-align: right;">Page 57</p> <p>1 well as the requirements of the SOP at that 2 time.</p> <p>3 MR. SLATER: Move to strike.</p> <p>4 MR. BALL: Oppose the motion.</p> <p>5 MR. SLATER: Mr. Ball, he 6 hasn't answered the question.</p> <p>7 MR. BALL: I believe he has, at 8 least six or seven times.</p> <p>9 MR. SLATER: Tell me what I'm 10 missing about the -- is the answer yes 11 or no, then? Was this actually 12 utilized with the process change? 13 Because I can't figure it out from his 14 answer.</p> <p>15 Would you tell me what that 16 answer is?</p> <p>17 MR. BALL: Are you asking me or 18 are you asking the witness?</p> <p>19 MR. SLATER: I'm asking you, 20 because you keep saying his answer is 21 responsive. So tell me whether or not 22 the answer was yes or no.</p> <p>23 MR. BALL: I'm not going to -- 24 I'm not here to answer questions,</p>

<p>1 Adam. I'm sorry you don't like the 2 answer you're getting from the 3 witness.</p> <p>4 MR. SLATER: I don't not like 5 the answer. He won't answer the 6 question.</p> <p>7 MR. BALL: Adam, I'm sorry you 8 don't like the answer. Again, you can 9 take it up with the Court.</p> <p>10 MR. SLATER: Is that what you 11 want me to do?</p> <p>12 MR. BALL: I want you to -- I 13 don't want you to keep asking that 14 same question over and over again 15 because you don't like the answer 16 you're given.</p> <p>17 MR. SLATER: It's not that I 18 don't like it. It's that he won't 19 answer the question, and I can't 20 understand what he's saying. He's not 21 addressing what I'm asking.</p> <p>22 I mean, I think there's some 23 obligation by a lawyer to tell their 24 client to be responsive in a federal</p>	<p>Page 58</p> <p>1 guideline is part of the SOP. I want to find 2 out, which part are you referring to?</p> <p>3 MR. SLATER: Mr. Interpreter, I 4 don't understand that. He's now 5 saying that he doesn't understand your 6 interpretation, and he's asking me to 7 fix your interpretation?</p> <p>8 What's going on here? I mean, 9 is that what he actually just said?</p> <p>10 A. Your question was translated by 11 the interpreter, but it was very long.</p> <p>12 Through the interpreter, I heard that you 13 referred to this guideline as part of the 14 SOP, so I just wonder, which part of the SOP 15 are you referring to?</p> <p>16 MR. SLATER: Move to strike all 17 this nonresponsive evasion.</p> <p>18 MR. BALL: Oppose the motion.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Was this guideline utilized in 21 connection with the zinc chloride process 22 change? Yes or no.</p> <p>23 MR. BALL: Objection to form.</p> <p>24 A. During the zinc chloride</p> <p>Page 60</p>
<p>1 proceeding.</p> <p>2 MR. BALL: Adam, I believe he 3 is being responsive. He's answering 4 the question to the best of his 5 ability.</p> <p>6 MR. SLATER: Really?</p> <p>7 MR. BALL: Yes.</p> <p>8 MR. SLATER: Okay. We'll try 9 it one last time, and then we'll have 10 our nice record.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Mr. Dong, was this guideline 13 utilized as part of the evaluation of 14 potential genotoxic impurities for the zinc 15 chloride process change? Yes or no.</p> <p>16 And I'm asking you to either 17 say yes or no.</p> <p>18 MR. BALL: Objection.</p> <p>19 You don't get to tell the 20 witness how to answer a question, 21 Adam.</p> <p>22 Objection to form.</p> <p>23 A. Your question is quite long. I 24 just heard from the interpreter that this</p>	<p>Page 59</p> <p>1 process change, we conducted the 2 corresponding work based on the requirements 3 of ICH at that time, as well as the 4 requirements of the SOP at that time.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Was this guideline one of those 7 SOPs that was utilized?</p> <p>8 A. Judging from what is shown on 9 the screen, I cannot tell the effective date 10 of this SOP. I need to review the whole 11 document in order to understand this SOP.</p> <p>12 MR. SLATER: Let's go off the 13 record. I think it's time for a 14 break, right?</p> <p>15 MR. BALL: It is time for a 16 break.</p> <p>17 THE VIDEOGRAPHER: The time is 18 9:35 a.m. Off the record.</p> <p>19 (Whereupon, a recess was 20 taken.)</p> <p>21 THE VIDEOGRAPHER: The time is 22 9:49 a.m. Back on the record.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. The metadata for this document</p> <p>Page 61</p>

<p>1 says it was modified on June 17, 2011. I'm 2 just telling you what the metadata says 3 provided by your lawyer.</p> <p>4 Knowing that and looking at the 5 document, you can look at it and tell me 6 whether or not this guideline was applied to 7 the zinc chloride process change for 8 valsartan.</p> <p>9 MR. BALL: Objection to form.</p> <p>10 A. Judging from what has been 11 shown on the screen, I cannot give you an 12 accurate answer.</p> <p>13 As for the process change for 14 valsartan, we conducted the corresponding 15 work based on the requirements of ICH then 16 and the requirements of SOP then.</p> <p>17 MR. SLATER: Move to strike 18 from "as for" forward.</p> <p>19 MR. BALL: Oppose the motion.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. What do you need to see in 22 order to answer the question?</p> <p>23 A. What is your question?</p> <p>24 MR. SLATER: I'm going to take</p>	<p>Page 62</p> <p>1 actually. 2 THE STENOGRAFHER: 194. 3 (Whereupon, Exhibit Number 4 ZHP-194 was marked for 5 identification.)</p> <p>6 MR. SLATER: So let's put up 7 Exhibit 194, which is ZHP00000161.</p> <p>8 And we're going to also mark as 9 Exhibit 195 the English version of 10 this document, which is ZHP01843066 11 through 3119, which I suppose we can 12 put into the chat so if defense 13 counsel wants to look at the document 14 I'm going to be using to refer to, 15 he'll have the ability to do that. 16 (Whereupon, Exhibit Number 17 ZHP-195 was marked for 18 identification.)</p> <p>19 MR. BALL: It's not up in the 20 chat yet, Adam, but go ahead and get 21 started.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Do you see Exhibit 195, titled 24 "Change Request Form"?</p>
<p>1 that as the witness has been asked 2 enough times, he's going to refuse to 3 answer and/or he's unprepared as a 4 30(b)(6).</p> <p>5 We're going to move to the next 6 document, and that's how we're going 7 to conduct ourselves today.</p> <p>8 MR. BALL: Objection.</p> <p>9 MR. SLATER: Take the document 10 down. We've made a full record on 11 that issue with that document. I 12 think that's sufficient to establish 13 what's going on here.</p> <p>14 Now, what we're going to do 15 next is pull up -- I'm going to be 16 working with two documents. We have 17 an English version and we have a 18 Chinese version, both of which were 19 provided by ZHP. I'm letting counsel 20 know so they know what's going on.</p> <p>21 So I'm going to put on the 22 screen -- what's the next exhibit? 23 193 or 194?</p> <p>24 I'm asking the court reporter,</p>	<p>Page 63</p> <p>1 A. Indeed, on the screen there's a 2 document shown to me. However, I cannot tell 3 from the screen the exhibit number.</p> <p>4 Q. Do you see the "Title: Change 5 Request Form" right there at the top of the 6 document?</p> <p>7 A. In this document, on the upper 8 part of this page, first row, middle column, 9 in Chinese it says "Change Request Form."</p> <p>10 Q. Sir, I'd appreciate it if you 11 can just answer "yes." It would be easier if 12 you just say "yes" instead of repeating my 13 question and saying -- and rereading the 14 whole question back as your answer.</p> <p>15 A. I will tell you the truth.</p> <p>16 Q. Section 1, the Change Title is 17 "Process Change for Valsartan Process II," 18 correct?</p> <p>19 MR. BALL: Mr. Hobbs, it's 20 still not up in the chat.</p> <p>21 Go ahead.</p> <p>22 MR. SLATER: It's ZHP01843066.</p> <p>23 It's not a question for the 24 witness. That's for my team, just to</p>

<p>1 make sure they have the right one. 2 Okay. What are we doing? 3 MR. BALL: The only thing 4 that's up in the chat is the ZH -- is 5 the Bates number for it. There's no 6 actual document. 7 MS. CALDERON: Mr. Ball, this 8 is Cheryll Calderon. 9 The exhibit link was available 10 in the chat. That's a public link for 11 you and your witness. 12 MR. BALL: I just tried to -- 13 MS. CALDERON: So it's that 14 thing. 15 MR. BALL: Oh. Hold on. 16 Got it. Okay. Sorry. 17 BY MR. SLATER: 18 Q. Okay. Mr. Dong, are you 19 familiar with this document, which is the 20 "Process Change for Valsartan Process II"? 21 Are you familiar with the 22 document? 23 A. On this page, the table where 24 it says "Change Title," next to it, it says</p>	<p>Page 66</p> <p>1 MR. BALL: I'm not representing 2 anything. Ask him whether or not it 3 is. 4 MR. SLATER: Counsel, we just 5 don't agree. It's not a legitimate 6 objection. 7 MR. BALL: That's a -- 8 MR. SLATER: I'll ask a 9 different question, because we all 10 know it's the final version. So he 11 can say this version all he wants, but 12 we'll move on. 13 BY MR. SLATER: 14 Q. This is the change request form 15 for the change to the zinc chloride -- 16 withdrawn. 17 This is the change request form 18 for the zinc chloride process for valsartan, 19 correct? 20 MR. SLATER: You know what? 21 Stop. Stop. Time out. Withdrawn. 22 Withdrawn. 23 You know what? I got this 24 figured out now. Thank you, Rick. I</p>
<p>1 "Process Change for Valsartan Process II." 2 Q. The effective date is June 15, 3 2011, correct? Do you see that at the top 4 right? 5 A. In the table, on the upper 6 right corner, there is an effective date 7 which says June 15, 2011. However, this 8 effective date is not the effective date of 9 the process change; rather, it is the 10 effective date of this version of Change 11 Request Form. 12 Q. This is the final version of 13 this document, correct? 14 MR. BALL: Objection to form. 15 MR. SLATER: One second. 16 What's the objection? 17 MR. BALL: Adam, you haven't 18 laid a foundation. Ask -- you know, 19 every time you say "correct," that's 20 an improper way to form the question. 21 You know it and I know it. 22 MR. SLATER: Are you 23 representing this isn't the final 24 version of the document?</p>	<p>Page 67</p> <p>1 got it. We're good now. 2 BY MR. SLATER: 3 Q. Look in the left-hand column to 4 the word "Proposed." Do you see that line 5 that says "Proposed"?</p> <p>6 A. Can you scroll up the screen a 7 little bit?</p> <p>8 Yes, I see it.</p> <p>9 Q. And it then says next to that, 10 "Process II crude product preparation process 11 would use zinc chloride as catalyst." 12 Correct?</p> <p>13 A. In this table, in the line of 14 proposed change, next to the word "Proposed," 15 there was a sentence written in Chinese which 16 says "Process II crude product preparation 17 process would use zinc chloride as catalyst." 18 This is just one sentence of 19 the content in that entry.</p> <p>20 MR. SLATER: Move to strike the 21 "This is just one sentence" part.</p> <p>22 MR. BALL: Objection to form. 23 Oppose the motion.</p> <p>24 ///</p>

<p>1 BY MR. SLATER:</p> <p>2 Q. Mr. Dong, I asked you a bunch 3 of times, can you just answer with a "yes" if 4 the answer is a yes, instead of repeating the 5 whole question, please?</p> <p>6 A. I will tell you the truth.</p> <p>7 Q. Looking down --</p> <p>8 MR. SLATER: Scroll down, 9 Cheryll, further down.</p> <p>10 Okay. Perfect.</p> <p>11 Q. Looking now at the box towards 12 the bottom, No. 4, it says, "If it is the 13 critical change?" And it says "Yes."</p> <p>14 Do you see that?</p> <p>15 A. At the bottom of this page, on 16 line 4, when it was asked if this is the 17 critical change, indeed, the box for "Yes" 18 was checked.</p> <p>19 Q. At the very bottom of the 20 page --</p> <p>21 MR. SLATER: Scroll down, 22 Cheryll, to the very bottom.</p> <p>23 Okay. Stop.</p> <p>24 Q. At the very bottom of the page,</p>	<p>Page 70</p> <p>1 was not checked.</p> <p>2 MR. SLATER: Scroll down, 3 please, Cheryll.</p> <p>4 A little more. More. A little 5 more.</p> <p>6 Okay. Perfect.</p> <p>7 Q. There's a box that says "Change 8 control Related Department(s)," and for the 9 "Process Change," a series of departments is 10 checked, correct?</p> <p>11 Actually, you know what?</p> <p>12 Withdraw that question. Forget it. I don't 13 care.</p> <p>14 Looking now at the Explanation 15 Section, this provides the explanation for 16 why this was being done, correct?</p> <p>17 MR. BALL: Objection to form.</p> <p>18 A. On the screen in the 19 Explanation Section, there is a paragraph 20 written in Chinese.</p> <p>21 MR. SLATER: Move to strike.</p> <p>22 MR. BALL: Oppose the motion.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Sir, did I ask you what</p>
<p>1 it says in the bottom left "Reference: 2 change control procedure (SMP-018)," correct?</p> <p>3 A. On the bottom of the screen, 4 there is a line that says in Chinese, 5 "Reference document: change control procedure 6 (SMP-018)."</p> <p>7 Q. That means that SMP applied to 8 this change request, correct?</p> <p>9 A. The SMP in this document is the 10 reference for the platform of -- not 11 platform -- template, rather, of this 12 document.</p> <p>13 Q. Go on to the next page, please, 14 page 2.</p> <p>15 Box 2, "Change Control 16 Classification," the box checked is "Critical 17 Change," correct?</p> <p>18 A. On the screen in the line of 19 "Change Control Classification," "Critical 20 Change" was indeed checked.</p> <p>21 Q. The second box for "Minor 22 Change" was not checked, correct?</p> <p>23 A. In the line of "Change Control 24 Classification," the option "Minor Change"</p>	<p>Page 71</p> <p>1 language it's written in?</p> <p>2 A. I will tell the truth.</p> <p>3 Q. You will tell the truth? I 4 need you to answer my questions. I didn't 5 ask you what language it's written in, so I 6 don't understand why you told me that. 7 Telling the truth is actually answering the 8 question responsively.</p> <p>9 MR. BALL: Objection.</p> <p>10 Harassment.</p> <p>11 MR. SLATER: It's not 12 harassment, because, Counsel, you're 13 sitting there smiling, as if you think 14 this is a good idea that your client 15 has been doing this for over two hours 16 and has taken most of the time with 17 nonresponsive answers.</p> <p>18 MR. BALL: Adam, I cannot help 19 the questions you ask.</p> <p>20 MR. SLATER: No, he's not 21 answering.</p> <p>22 Did I ask him what language it 23 was written in? No. So why don't you 24 tell him, please, "Sir, don't tell him</p>

<p>1 what language it's in if he didn't ask 2 that question."</p> <p>3 I mean, I don't understand why 4 you wouldn't want to cooperate in good 5 faith.</p> <p>6 MR. BALL: We are cooperating 7 in good faith.</p> <p>8 MR. SLATER: No, you're not.</p> <p>9 MR. BALL: It's your questions.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Okay. So now we'll go to the 12 next question.</p> <p>13 In the Explanation Section, it 14 says, "This is a process change for current 15 Valsartan manufacturing process II," then in 16 parentheses, "(triethylamine hydrochloride 17 process) in Workshop II. In crude product 18 preparation process the catalyst for 19 tetrazole forming reaction is changed from 20 triethylamine hydrochloride to zinc chloride. 21 In order to enhance conversion rate, reduce 22 the level of D-valsartan via racemization and 23 improve the yield or output quality of crude 24 product. The bond acid reagent in acylation</p>	<p>Page 74</p> <p>1 section in the Explanation Section, the 2 description in Chinese is basically 3 consistent with the interpreter's translation 4 of the opposing counsel's question.</p> <p>5 Q. What is "process validation" as 6 that term is used there?</p> <p>7 A. Process validation is one of 8 the managed activities under GMP.</p> <p>9 Q. What is process validation 10 supposed to accomplish?</p> <p>11 A. The purpose of a process 12 validation depends on the description 13 specified in the process change plan. Or 14 process validation plan, that is.</p> <p>15 Q. Go to the next page.</p> <p>16 Looking at Section 3 for the 17 quality control department, in the 18 Explanation Section it says, "The residue of 19 zinc chloride and residue of solvents used in 20 the process need to be tested for quality 21 review. The relevant method validation 22 should be completed."</p> <p>23 Do you see that?</p> <p>24 A. On the screen, under the</p>
<p>1 reaction process is changed to reduce cost. 2 The process validation studies would be 3 arranged in Workshop II of Chuannan East 4 Zone."</p> <p>5 My only question is, did you 6 see what I just read? It's a yes-or-no 7 question.</p> <p>8 MR. BALL: Objection to form.</p> <p>9 A. What I read in the Explanation 10 Section on the screen is basically consistent 11 from the interpreter's interpretation of the 12 opposing counsel's question.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Let's go to the next page, 15 page 3.</p> <p>16 Under the "TE" section, in the 17 Explanation Section it says, "This change 18 request is agreed. The process validation 19 should be performed. The manufacturing 20 process instructions and batch record shall 21 be revised. The stability studies shall be 22 conducted. Yang Kai, November 27, 2011."</p> <p>23 Do you see what I just read?</p> <p>24 A. On the screen under the TE</p>	<p>Page 75</p> <p>1 section of quality control department in the 2 Explanation Section, the description in 3 Chinese is basically consistent with the 4 interpretation of the plaintiffs' original 5 statement.</p> <p>6 Q. The reason this -- rephrase. 7 One of the reasons for this 8 quality review is to identify any impurities 9 due to the new process, correct?</p> <p>10 MR. BALL: Objection to form.</p> <p>11 A. I don't understand what the 12 opposing counsel is referring to by "this 13 review."</p> <p>14 BY MR. SLATER:</p> <p>15 Q. The quality review that is 16 referenced in the Explanation Section that I 17 just read.</p> <p>18 A. Can you repeat the complete 19 question again?</p> <p>20 MR. SLATER: Read it back to 21 him, please. The interpreter. You 22 can read it back to him, right? I 23 don't need to ask it again. You have 24 it. Just please read it back to him</p>

<p>1 again.</p> <p>2 THE INTERPRETER: For the</p> <p>3 record, the interpreter is asked to</p> <p>4 repeat the rendition of a previous</p> <p>5 question.</p> <p>6 A. The QC department will, based</p> <p>7 on its departmental responsibility as well as</p> <p>8 the content of the change application, to</p> <p>9 conduct an assessment.</p> <p>10 MR. SLATER: Move to strike.</p> <p>11 MR. BALL: Oppose the motion.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Let's go now to the bottom of</p> <p>14 the document, the regulatory affairs section,</p> <p>15 please.</p> <p>16 Looking at the bottom of the</p> <p>17 document, the regulatory affairs section, in</p> <p>18 the explanation, the third sentence says,</p> <p>19 "This change is critical, and CEP major</p> <p>20 changes procedure would be applied."</p> <p>21 That's what it says, right?</p> <p>22 A. On the screen in the section of</p> <p>23 RA department in the Explanation Section, the</p> <p>24 third sentence here in this Chinese paragraph</p>	<p>Page 78</p> <p>1 A. This process change, as well as</p> <p>2 the work we conducted, were done based on the</p> <p>3 requirements of the SOP and the GMP.</p> <p>4 MR. SLATER: Move to strike.</p> <p>5 MR. BALL: Oppose the motion.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. I would appreciate it if you</p> <p>8 would make an effort to answer my question,</p> <p>9 Mr. Dong.</p> <p>10 A. I will tell the truth.</p> <p>11 Q. Okay. Then let's tell the</p> <p>12 truth in answering this question and actually</p> <p>13 answer the question I ask. That's what I'm</p> <p>14 asking.</p> <p>15 MR. BALL: Objection to form.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. I'll try it one last time with</p> <p>18 you on this one. New question.</p> <p>19 MR. SLATER: Interpreter, are</p> <p>20 you going to have to interpret what I</p> <p>21 just did? Because if you do, I'd</p> <p>22 rather you do it before I ask the</p> <p>23 question.</p> <p>24 Q. Line number 23 required that</p> <p>Page 80</p>
<p>1 says, "This change is critical, and CEP" -- I</p> <p>2 don't know how to pronounce the next English</p> <p>3 word, which is followed by "changes would be</p> <p>4 applied."</p> <p>5 MR. SLATER: Let's go to the</p> <p>6 next page. Perfect.</p> <p>7 Q. Looking now at Section 3, the</p> <p>8 quality assurance section, line 23 says,</p> <p>9 "Evaluate if it againsts cGMP code; (if so,</p> <p>10 describe the article and reject it)." And</p> <p>11 the box for "No" is checked?</p> <p>12 Do you see that?</p> <p>13 A. As shown on the screen, in the</p> <p>14 section for quality assurance department,</p> <p>15 line 23, it says here in Chinese, "Evaluate</p> <p>16 if it is against the cGMP code; (if so,</p> <p>17 describe the article that is against the code</p> <p>18 and reject that change request)." And the</p> <p>19 "No" box next to it was checked.</p> <p>20 Q. If this change was against cGMP</p> <p>21 code, it was supposed to be rejected. That</p> <p>22 is what that says, correct?</p> <p>23 MR. BALL: Objection.</p> <p>24 Foundation.</p>	<p>Page 79</p> <p>1 the change be rejected if this process change</p> <p>2 did not comply in any way with cGMP, correct?</p> <p>3 MR. BALL: Objection to form.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Yes or no.</p> <p>6 A. We conducted our work for any</p> <p>7 changes based on the requirements of our SOP</p> <p>8 as well as the GMP.</p> <p>9 MR. SLATER: Move to strike.</p> <p>10 That's not what I asked.</p> <p>11 MR. BALL: Oppose the motion.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Mr. Dong, you took an oath to</p> <p>14 answer these questions, so please answer the</p> <p>15 question.</p> <p>16 MR. BALL: Objection.</p> <p>17 A. I will tell the truth.</p> <p>18 For the process changes, we</p> <p>19 conducted our work under the condition of</p> <p>20 being in compliance with the SOP and the GMP.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. If your company did not comply</p> <p>23 with your SOPs -- rephrase.</p> <p>24 If your company did not comply</p> <p>Page 81</p>

<p>1 with GMP, the process change never should 2 have been -- let me rephrase it. Let's get 3 to the cut. Let's get to it. Hang on. 4 Your company was legally 5 required to comply with GMP with the process 6 change, correct? 7 MR. BALL: Objection to form. 8 A. What legal requirements are you 9 referring to? 10 BY MR. SLATER: 11 Q. The regulations of the United 12 States of America, including the FDA. 13 MR. BALL: Objection to form. 14 A. We conducted our work for our 15 process change under the premise that they 16 are in compliance with the requirement of 17 GMP, including the US GMP. 18 MR. SLATER: Move to strike. 19 MR. BALL: Oppose the motion. 20 BY MR. SLATER: 21 Q. What I asked is if your company 22 was required to comply with GMP in order to 23 be in compliance with United States law. 24 MR. BALL: Objection to form.</p>	<p>Page 82</p> <p>1 Explanation Section on the first line, there 2 was a sentence in Chinese which fits this 3 description. 4 Q. With regard to this change for 5 this API, what was the purpose of the process 6 validation? 7 A. As for the purpose of the 8 process validation for valsartan this time, I 9 need to check the process validation plan. 10 Q. What was the purpose of the 11 process validation? 12 A. Which process validation are 13 you referring to? 14 Q. The process validation referred 15 to in this document for this process change 16 that you were designated by your company to 17 testify about. 18 A. As for the purpose of the 19 process validation for this proposed process 20 change for the valsartan, I need to check the 21 process validation plan in order to provide 22 you with an accurate answer. 23 In general, process validation 24 is to confirm whether the product can be</p>
<p>1 BY MR. SLATER: 2 Q. I didn't ask if you did comply; 3 I asked if you were required to comply. Yes 4 or no. 5 MR. BALL: Objection to form. 6 A. We would conduct our work in 7 compliance with the corresponding 8 requirements of GMP and SOP. 9 MR. SLATER: Move to strike. 10 MR. BALL: Oppose the motion. 11 MR. SLATER: All right. We'll 12 just keep making our record. I mean, 13 I just can't get an answer to a 14 question from this witness. 15 Scroll down a little more, 16 Cherryl, please. 17 Thanks. Perfect. 18 Q. Here on page 5 of this document 19 in the Explanation Section, number 1, it says 20 "Technology department prepare process 21 validation protocol, and organize process 22 validation." 23 Do you see that? 24 A. On the screen, in the</p>	<p>Page 83</p> <p>1 Page 84</p> <p>1 stably manufactured under the current scale 2 of the process. 3 Q. Mr. Dong, did you say you have 4 two computer screens in front of you? 5 A. That is correct. 6 Q. So you can actually -- when I 7 ask a yes-or-no question, you can actually 8 answer the question with a yes or no when you 9 choose to, apparently, is that correct? 10 MR. BALL: Objection to form. 11 A. Can you repeat your question 12 here? 13 BY MR. SLATER: 14 Q. No, I can't. 15 Your company was supposed to 16 perform a risk assessment as part of the 17 process validation -- rephrase. 18 Your company was supposed to 19 perform a risk assessment as part of the 20 process change evaluation, correct? 21 MR. BALL: Objection to form. 22 A. What do you mean by "was 23 supposed to"? 24 ///</p>

<p>1 BY MR. SLATER:</p> <p>2 Q. Required to.</p> <p>3 A. We conducted corresponding work</p> <p>4 based on the requirements of ICH and SOP.</p> <p>5 MR. SLATER: Move to strike.</p> <p>6 MR. BALL: Oppose the motion.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. I didn't ask you what you did;</p> <p>9 I asked you what you were required to do. So</p> <p>10 please answer that question.</p> <p>11 A. We conducted corresponding work</p> <p>12 based on the requirements of ICH and SOP. I</p> <p>13 mean the ICH and SOP at that time.</p> <p>14 MR. SLATER: Move to strike.</p> <p>15 MR. BALL: Oppose the motion.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Was your company required to</p> <p>18 perform a risk assessment in connection with</p> <p>19 the process change to the zinc chloride</p> <p>20 process? Yes or no.</p> <p>21 A. In 2011 for the process change</p> <p>22 using zinc chloride for valsartan, we</p> <p>23 conducted corresponding work based on the</p> <p>24 requirements of ICH and SOP at that time.</p>	<p>Page 86</p> <p>1 What is the purpose of</p> <p>2 Attachment 2 as part of this document? Why</p> <p>3 is it there?</p> <p>4 A. On the screen it is shown the</p> <p>5 Attachment 2 to the change request form for</p> <p>6 the zinc chloride process change in 2011.</p> <p>7 Attachment 2 is the change action list.</p> <p>8 Q. What is the change action list?</p> <p>9 What is the significance of that?</p> <p>10 A. The change action list details</p> <p>11 the actions each department needed to take.</p> <p>12 Q. Those actions had to be taken</p> <p>13 in order for the change to be approved,</p> <p>14 correct?</p> <p>15 A. The change action list is</p> <p>16 required by the SOP as one of the</p> <p>17 requirements.</p> <p>18 Q. Item number 5 --</p> <p>19 MR. SLATER: Let's go down to</p> <p>20 number 5, please, Cheryll.</p> <p>21 Q. Item number 5 indicates that</p> <p>22 regulatory affairs updates the DMF and</p> <p>23 notifies customers and authorities, correct?</p> <p>24 A. The Chinese writing in item</p>
<p>1 MR. SLATER: Move to strike.</p> <p>2 MR. BALL: Oppose the motion.</p> <p>3 MR. SLATER: For the</p> <p>4 interpreter, I think we might be at</p> <p>5 your time. I can continue, but I just</p> <p>6 want to make sure. Someone just</p> <p>7 pinged me that you might be up to your</p> <p>8 time.</p> <p>9 MR. BALL: Yeah, we're at</p> <p>10 63 minutes, Adam.</p> <p>11 MR. SLATER: All right. Let's</p> <p>12 go off the record.</p> <p>13 THE VIDEOGRAPHER: The time is</p> <p>14 10:56 a.m. Off the record.</p> <p>15 (Whereupon, a recess was</p> <p>16 taken.)</p> <p>17 THE VIDEOGRAPHER: The time is</p> <p>18 11:15 a.m. Back on the record.</p> <p>19 MR. SLATER: Let's go now,</p> <p>20 Cheryll, please, to Attachment 2.</p> <p>21 Perfect.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. This is Attachment 2 to the</p> <p>24 change request form.</p>	<p>Page 87</p> <p>1 number 5 on the screen does say so.</p> <p>2 Q. Go to the next page, please.</p> <p>3 The Bates number is 073, are the last three</p> <p>4 digits.</p> <p>5 MR. SLATER: And please go to</p> <p>6 item 5 as well, Cheryll.</p> <p>7 Q. This page indicates that all</p> <p>8 actions had been implemented, the change</p> <p>9 control could be approved and closed,</p> <p>10 correct?</p> <p>11 A. I'm sorry. I'm not sure which</p> <p>12 section the plaintiffs' attorney is referring</p> <p>13 to specifically.</p> <p>14 Q. In the top section, number 1,</p> <p>15 "If all actions have been implemented?" It</p> <p>16 says "Yes."</p> <p>17 Number 2 says, "If approve to</p> <p>18 close up the change control?" And it says</p> <p>19 "Yes." Correct?</p> <p>20 A. That is correct.</p> <p>21 Q. Number 3 says that the first</p> <p>22 product batch number produced after the</p> <p>23 change would be number C5355-12-001, correct?</p> <p>24 A. That is correct.</p>

<p>1 Q. Going now in the Explanation 2 Section, number 5 says, "December 20, 2013, 3 regulatory affairs completed the DMF update, 4 submission to authority and notification to 5 customers." Correct? 6 A. On the screen in the 7 Explanation Section, there is a paragraph, 8 item number 5, it says, "On December 20, 9 2013, the regulatory affairs department 10 completed the update of the DMF document and 11 submitted it to the authority, in addition to 12 notification to the customers." 13 Q. Why was it required as part of 14 this process change to update the DMF? 15 A. Our process change requires the 16 approval from FDA, per FDA's regulations, in 17 order to implement the change in the US 18 market. That's the reason why the DMF 19 document needed to be updated. 20 Q. Are you aware that the FDA 21 doesn't approve a DMF? 22 MR. BALL: Objection to form. 23 Outside the scope of the 30(b)(6). 24 I assume you're asking him in</p>	<p>Page 90</p> <p>1 dialogue between the counsel? 2 MR. SLATER: No. No. 3 A. I don't remember the pending 4 question. 5 BY MR. SLATER: 6 Q. Are you aware that the FDA does 7 not approve a DMF? It's not for that 8 purpose? 9 MR. BALL: Same objection. 10 BY MR. SLATER: 11 Q. Are you aware of that? 12 A. The question from the 13 plaintiffs' attorney was indeed beyond the 14 scope of my testimony as the corporate 15 witness. 16 However, based on the personal 17 understanding, for our process change, we 18 were obligated to submit the updated DMF 19 document to FDA for the authority. 20 Q. You were required by your 21 internal standard operating procedures, but 22 the FDA did not actually approve the DMF, 23 correct? 24 MR. BALL: Objection to form,</p>
<p>1 his individual capacity, Adam? 2 MR. SLATER: I'm asking -- it's 3 part of their change control request 4 document. It's part of his topic. 5 This document is at the heart of his 6 topic. I just -- 7 MR. BALL: Adam, I'm asking -- 8 Adam, I'm asking you if you're asking 9 him in his individual capacity whether 10 or not he knows it's something that 11 FDA requires or doesn't require. 12 MR. SLATER: I'm asking him in 13 his capacity as a 30(b)(6) witness who 14 just made an affirmative statement in 15 his capacity as a 30(b)(6) witness. 16 He said something, and I'm 17 asking him a question about what he 18 said as an answer to a question within 19 the scope of his topic. 20 MR. BALL: I believe it's 21 outside the scope. 22 He can answer. 23 THE INTERPRETER: Counsel, does 24 the interpreter need to translate the</p>	<p>Page 91</p> <p>1 and outside the scope. 2 A. Counsel's question was indeed 3 beyond the scope of my testimony as a 4 corporate witness. 5 MR. BALL: He should answer 6 anyway, if he can. 7 A. However, to the best of my 8 personal knowledge, it was our regulatory 9 affairs department's responsibility to 10 conduct the communication between ZHP and the 11 authorities. That's their job description. 12 BY MR. SLATER: 13 Q. We'll come back to the DMF in a 14 second. 15 Are you -- you said before 16 you're looking at two screens, right? 17 A. That is correct. 18 Q. All right. What's on the two 19 screens? 20 A. The computer I'm using right 21 now is the one that I use to conduct this 22 Zoom meeting. On the screen it shows the 23 exhibit. 24 The other computer shows the</p>

<p>1 screen saver right now. There's nothing 2 ongoing in the other computer. 3 Q. When I asked you the questions 4 about the DMF, why did you say that the 5 question was beyond the scope of the topics 6 of your testimony as a corporate witness? 7 Why did you say that? 8 A. As a corporate witness, I am 9 supposed to, or I am responsible for the 10 discussion regarding those topics. 11 Q. Do you remember the beginning 12 of the deposition when you couldn't remember 13 the topics? 14 MR. BALL: Objection to form. 15 BY MR. SLATER: 16 Q. Now you're an expert on the 17 topics -- 18 MR. BALL: Objection to form. 19 BY MR. SLATER: 20 Q. -- and you repeat objections? 21 Why is that, sir? 22 MR. BALL: Objection to form. 23 A. As for the questions I'm 24 supposed to answer as a corporate witness, I</p>	<p>Page 94</p> <p>1 BY MR. SLATER: 2 Q. When you said the question was 3 beyond the scope of your testimony, did you 4 come up with that on your own, or were you 5 repeating the objection by your attorney? 6 MR. BALL: Objection to form. 7 A. I came up with the 8 corresponding judgment. That was because my 9 obligation was to answer the questions 10 related to the technical department. 11 As for the DMF document, that 12 was related to the regulatory affairs 13 activities. I believe the colleagues of mine 14 from the regulatory affairs department should 15 answer those questions. 16 BY MR. SLATER: 17 Q. The change request form -- 18 rephrase. 19 You agree with me that any 20 information put in that DMF based on this 21 change process needed to be completely 22 accurate, correct? 23 MR. BALL: Objection to form. 24 And outside of the scope of the</p> <p>Page 96</p>
<p>1 do have some understanding, or I may say I do 2 recall some of the topics. 3 However, if you ask me to 4 accurately recite all the topics I need to 5 respond to as a corporate witness or you want 6 me to give an accurate response to your 7 questions as to what topics I'm supposed to 8 answer as a corporate witness, I would like 9 you to present that document to me for my 10 response. 11 MR. BALL: And, for the record, 12 that was the first document that 13 Mr. Slater put up, and he did not show 14 any of the corporate topics. 15 MR. SLATER: I'm not really 16 sure why I would. Your client doesn't 17 read English. 18 MR. BALL: You could have had 19 them translated, Adam, by the 20 translator. That's why we have him. 21 MR. SLATER: I didn't think it 22 was necessary for what I wanted to ask 23 him. But thank you for your kind 24 advice.</p>	<p>Page 95</p> <p>1 30(b)(6) topics. 2 A. I do not understand what the 3 opposing counsel was referring to with regard 4 to any DMF information. 5 BY MR. SLATER: 6 Q. Okay. Go to the next page, 7 please. This is -- let me just get to it. 8 On the English, it's 074 is the 9 last three digits -- I'm not done. And in 10 the Chinese, it's 0169 are the last digits of 11 the Bates number. 12 Section -- rephrase. 13 The title of this page says 14 "Valsartan Process II (Zinc Chloride Process) 15 Changes Summary," and Section I is "Reasons 16 for Changes." 17 And it says in the first 18 paragraph, "There were some defects and 19 inadequacies for the previous manufacturing 20 process of Valsartan, such as the low yield 21 in some steps, high production cost, three 22 wastes pollution problems, etcetera." 23 Do you see where I just read? 24 A. On the screen, I did find what</p> <p>Page 97</p>

<p>1 the interpreter provided as the rendition.</p> <p>2 Q. In Section I on page Bates 0169</p> <p>3 under "Reasons for Changes," in the third</p> <p>4 line it says, "From 2010, ZHP had</p> <p>5 commissioned Shanghai SynCore Technologies,</p> <p>6 Inc. to optimize the previous synthesis</p> <p>7 process of Valsartan (Process II,</p> <p>8 Trimethylamine Hydrochloride Process),</p> <p>9 focusing on the new tetrazole formation</p> <p>10 process development of crude step."</p> <p>11 Do you see that? I want to ask</p> <p>12 you a question about it. Literally the</p> <p>13 question is, do you see that.</p> <p>14 A. On the screen, I do see the</p> <p>15 interpreter's rendition of the opposing</p> <p>16 counsel's statement. However, it is just one</p> <p>17 sentence in the paragraph under Section I.</p> <p>18 MR. SLATER: Move to strike</p> <p>19 that last part saying it was just one</p> <p>20 sentence.</p> <p>21 MR. BALL: Oppose the motion.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Further down in that paragraph,</p> <p>24 there's a reference to "the lab-scale studies</p>	Page 98	<p>1 interpreter, it says "Shanghai</p> <p>2 SynCore," so I don't know why you keep</p> <p>3 saying "Kesheng." I'm not sure where</p> <p>4 Kesheng is coming from. It says</p> <p>5 SynCore in this. I don't know what</p> <p>6 Kesheng is.</p> <p>7 THE INTERPRETER: For the</p> <p>8 record, the English document had a</p> <p>9 misinterpretation. The interpreter</p> <p>10 provided the rendition based on the</p> <p>11 witness' testimony, which was</p> <p>12 consistent with what's written here in</p> <p>13 Chinese.</p> <p>14 MR. SLATER: I mean, my</p> <p>15 checkers don't agree, but -- I don't</p> <p>16 know what to do.</p> <p>17 MR. BALL: Hey, Adam? To the</p> <p>18 best of my knowledge, it's referring</p> <p>19 to SynCore also. Just putting that</p> <p>20 out there.</p> <p>21 MR. SLATER: Yeah. I would</p> <p>22 think it's got to be accurate.</p> <p>23 MR. BALL: Right.</p> <p>24 MR. SLATER: If SynCore -- it</p>
<p>1 results (R&D report No.: SC-1141)."</p> <p>2 What does that mean, "lab-scale</p> <p>3 studies results"?</p> <p>4 A. On the screen under Section I,</p> <p>5 reasons for the change, the paragraph under</p> <p>6 it, in the last sentence there was this</p> <p>7 reference based on the lab study -- lab-scale</p> <p>8 study results SC-1141. That refers to the</p> <p>9 research and development report provided by</p> <p>10 Shanghai Kesheng Company Limited, Kesheng</p> <p>11 spelled as K-E-S-H-E-N-G Company Limited.</p> <p>12 MR. SLATER: Move to strike.</p> <p>13 MR. BALL: Oppose the motion.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. What was the purpose of the</p> <p>16 lab-scale studies results referred to under</p> <p>17 Section I where it says "Reasons for</p> <p>18 Changes"?</p> <p>19 A. The lab-scale study result</p> <p>20 mentioned in the Reasons for Changes under</p> <p>21 Section I of this document on the screen</p> <p>22 refers to the lab-scale study report provided</p> <p>23 by Kesheng, spelled as K-E-S-H-E-N-G.</p> <p>24 MR. SLATER: For the</p>	Page 99	<p>1 was carefully, I assume, translated</p> <p>2 into the English here.</p> <p>3 MR. BALL: Yeah. So, to the</p> <p>4 best of my knowledge, it's SynCore</p> <p>5 also. So...</p> <p>6 MR. SLATER: Okay. I guess</p> <p>7 I'll move to strike because I still</p> <p>8 don't --</p> <p>9 THE INTERPRETER: The</p> <p>10 interpreter --</p> <p>11 MR. SLATER: -- know what the</p> <p>12 purpose of the lab-scale studies was,</p> <p>13 but it's okay.</p> <p>14 THE INTERPRETER: The</p> <p>15 interpreter interprets what he hears.</p> <p>16 MR. SLATER: Yeah. No, I</p> <p>17 understand. I'm just -- we're trying</p> <p>18 to figure out why he's saying</p> <p>19 "Kesheng" when the official document</p> <p>20 from ZHP says "Shanghai SynCore" as</p> <p>21 the interpretation. So I'm trying to</p> <p>22 figure out why he'd be saying</p> <p>23 "Kesheng" if the English document says</p> <p>24 "Shanghai SynCore Technologies."</p>

<p>Page 102</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Let's go to Section II.</p> <p>3 MR. BALL: I'm sorry. What are</p> <p>4 we doing?</p> <p>5 MR. SLATER: Looking at Section</p> <p>6 II. Yeah, let me -- I'll start over.</p> <p>7 We're looking at Section II.</p> <p>8 I don't know where we're going</p> <p>9 there. You don't have to scroll down.</p> <p>10 MR. BALL: Yeah, I'm sorry. I</p> <p>11 thought you said "go back to." That's</p> <p>12 why I was confused.</p> <p>13 MR. SLATER: No, no. I'm</p> <p>14 talking to Cheryll. I actually didn't</p> <p>15 want to -- yeah, keep going a little</p> <p>16 bit more.</p> <p>17 Perfect. And you'll just walk</p> <p>18 down with me, Cheryll.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Under Section II, there's a box</p> <p>21 titled "Raw Materials Changes Comparison."</p> <p>22 Let's go to the next page now,</p> <p>23 where there's the comparison of the raw</p> <p>24 materials.</p>	<p>Page 104</p> <p>1 MR. SLATER: Move to strike</p> <p>2 from "however" forward.</p> <p>3 MR. BALL: Oppose the motion.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. The next line is "Sodium</p> <p>6 azide," and it says 112.5 kilograms is</p> <p>7 replaced by sodium azide 250 kilograms.</p> <p>8 Do you see that?</p> <p>9 A. On the screen, in the box for</p> <p>10 crude products step, there is a line where</p> <p>11 the Chinese indicates that sodium azide was</p> <p>12 increased from 112.5 kilograms to</p> <p>13 250 kilograms.</p> <p>14 Q. If you go down three more</p> <p>15 boxes, it indicates that sodium nitrite was</p> <p>16 increased from 100 kilograms to</p> <p>17 250 kilograms, correct?</p> <p>18 A. On the screen, in the box for</p> <p>19 crude product step, there was a line where</p> <p>20 the Chinese description indicates the amount</p> <p>21 of sodium nitrite used was increased from</p> <p>22 100 kilograms to 250 kilograms.</p> <p>23 Q. And if we go up to the prior</p> <p>24 box for a moment -- you can leave it where it</p>
<p>Page 103</p> <p>1 I'm withdrawing the question.</p> <p>2 I'm going to go to the next section. I'm</p> <p>3 sorry. I'm going to go to the next section.</p> <p>4 Looking now at the box titled 2</p> <p>5 on -- 170 is the Bates number. The box</p> <p>6 starts on that page, and the title is "Main</p> <p>7 Materials Charging and Production Capacity</p> <p>8 Comparison." And if we scroll to the next</p> <p>9 page --</p> <p>10 MR. SLATER: I want to go to</p> <p>11 the middle of the page, please.</p> <p>12 Q. If you go down to the "Crude"</p> <p>13 section, this indicates that triethylamine</p> <p>14 hydrochloride was replaced with zinc</p> <p>15 chloride.</p> <p>16 Do you see that?</p> <p>17 A. On the screen in a box for</p> <p>18 crude product step, the description in</p> <p>19 Chinese does say that triethylamine</p> <p>20 hydrochloride was replaced with zinc</p> <p>21 chloride.</p> <p>22 However, the title of this</p> <p>23 table that the opposing counsel just referred</p> <p>24 to cannot be seen on the screen.</p>	<p>Page 105</p> <p>1 is because we can see the last entry -- this</p> <p>2 indicates in the "Acylation" section that</p> <p>3 DMF, dimethylformamide, had been added to the</p> <p>4 process, correct?</p> <p>5 A. On the screen, in the box for</p> <p>6 the staff of acetylation --</p> <p>7 THE INTERPRETER: The</p> <p>8 interpreter's correction.</p> <p>9 A. On the screen, in the box of</p> <p>10 "Acylation," there is a line where it</p> <p>11 indicated that DMF was added to the process.</p> <p>12 Q. As part of the change control</p> <p>13 process, these changes in the substances used</p> <p>14 to manufacture valsartan had to be evaluated</p> <p>15 for impurities, correct?</p> <p>16 MR. BALL: Objection to form.</p> <p>17 A. We conducted corresponding work</p> <p>18 based on the requirements of ICH and SOP.</p> <p>19 What I mean is the ICH and SOP at that time.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. So your answer is yes, you were</p> <p>22 required to perform a risk assessment for</p> <p>23 potential impurities resulting from these</p> <p>24 changes in the substances used to manufacture</p>

<p>1 valsartan, correct? 2 MR. BALL: Objection to form. 3 THE VIDEOGRAPHER: It's just 4 his connection. 5 MR. BALL: I was going to say, 6 did we just lose his connection? 7 THE VIDEOGRAPHER: That's his 8 internet lagging behind. We're going 9 to know in about five to ten seconds 10 if he disconnected or not, or whether 11 he regroups. 12 I think he's going to 13 disconnect. Do you guys want to go 14 off the record? 15 MR. BALL: Why don't we go off 16 the record. 17 THE VIDEOGRAPHER: The time is 18 12:04 p.m. Off the record. 19 (Off the record.) 20 THE VIDEOGRAPHER: The time is 21 12:05 p.m. We are back on the record. 22 A. I'm sorry, I just lost the 23 connection. Would the interpreter like me to 24 repeat my response?</p>	<p>Page 106</p> <p>1 sentences in this box. 2 MR. SLATER: Move to strike the 3 observation that "This is just one 4 sentence." 5 Q. I thank you for telling me 6 that. 7 MR. BALL: Oppose the motion. 8 BY MR. SLATER: 9 Q. Number 2 says, "Sodium azide 10 used for the quenching is increased due to 11 the increase of sodium azide." 12 That should actually say sodium 13 nitrite used for the quenching is increased, 14 correct? 15 A. On the screen, in a box for 16 crude product step, there is a sentence in 17 Chinese which says, "The amount of sodium 18 nitrite used in the quenching step was 19 increased because that was a corresponding 20 increase based on the increase of the charged 21 amount of sodium azide." 22 Over here the wording "sodium 23 nitrite used in the quenching" means the 24 amount of sodium nitrite used in the</p> <p>Page 108</p>
<p>1 BY MR. SLATER: 2 Q. Yes. 3 A. Just now the plaintiffs' 4 attorney failed to accurately describe what I 5 wanted to express. 6 What I wanted to express is 7 that in 2011 for the process change using 8 zinc chloride in the manufacturing of 9 valsartan, based on the ICH and SOP at that 10 time, we conducted corresponding work. 11 MR. SLATER: Move to strike. 12 MR. BALL: Oppose the motion. 13 BY MR. SLATER: 14 Q. Underneath the box where I was 15 just reading from, in number 1 it says that 16 "The tetrazole formation system is changed 17 and the quantity of sodium azide is 18 increased," correct? 19 A. On the screen, in the box for 20 crude product step, there is a sentence in 21 Chinese which says, "For crude product, the 22 tetrazole reaction system has changed. The 23 amount of sodium azide used is increased." 24 This sentence is just one sentence among many</p>	<p>Page 107</p> <p>1 quenching step. 2 Q. Thank you for that. 3 So in the Chinese, it's 4 accurate. The English translation said 5 "sodium azide used for the quenching." It 6 should have said "sodium nitrite"?</p> <p>7 A. I am sorry. I cannot read the 8 English version. The interpreter did not 9 translate the English version to me, so I 10 have no idea what the English version says.</p> <p>11 MR. SLATER: Go to, if we 12 could -- you know, I just looked at 13 what time it is. We can go off the 14 record and break for the night.</p> <p>15 MR. BALL: Okay. Can I get 16 when we go off how much time we've 17 gone total?</p> <p>18 THE VIDEOGRAPHER: We went for 19 four hours and 12 minutes.</p> <p>20 But the time is 12:14 p.m. We 21 are going off the record.</p> <p>22 (Whereupon, the deposition was 23 adjourned.)</p> <p>24</p> <p>Page 109</p>

<p>1 CERTIFICATE 2 3 I, MAUREEN O'CONNOR 4 POLLARD, Registered Diplomate 5 Reporter, Realtime Systems 6 Administrator, and Certified Shorthand 7 Reporter, do hereby certify that prior 8 to the commencement of the 9 examination, PENG DONG, was remotely 10 duly identified and sworn by me to 11 testify to the truth, the whole truth, 12 and nothing but the truth. 13 I DO FURTHER CERTIFY that 14 the foregoing is a verbatim transcript 15 of the testimony as taken 16 stenographically by and before me at 17 the time, place, and on the date 18 hereinbefore set forth, to the best of 19 my ability. 20 I DO FURTHER CERTIFY that 21 I am neither a relative nor employee 22 nor attorney nor counsel of any of the 23 parties to this action, and that I am 24 neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action. 25 MAUREEN O'CONNOR POLLARD 26 NCRA Registered Diplomate Reporter 27 Realtime Systems Administrator 28 Certified Shorthand Reporter 29 Notary Public 30 Dated: March 30, 2021</p>	<p>Page 110 1 ----- 2 E R R A T A 3 ----- 4 PAGE LINE CHANGE 5 ----- 6 REASON: _____ 7 REASON: _____ 8 REASON: _____ 9 REASON: _____ 10 REASON: _____ 11 REASON: _____ 12 REASON: _____ 13 REASON: _____ 14 REASON: _____ 15 REASON: _____ 16 REASON: _____ 17 REASON: _____ 18 REASON: _____ 19 REASON: _____ 20 REASON: _____ 21 REASON: _____ 22 23 24</p>
<p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the 9 errata sheet and date it. It will be 10 attached to your deposition. 11 It is imperative that you return 12 the original errata sheet to the deposing 13 attorney within thirty (30) days of receipt 14 of the deposition transcript by you. If you 15 fail to do so, the deposition transcript may 16 be deemed to be accurate and may be used in 17 court. 18 19 20 21 22 23 24</p>	<p>Page 111 1 2 3 4 I, _____, do 5 Hereby certify that I have read the foregoing 6 pages, and that the same is a correct 7 transcription of the answers given by me to 8 the questions therein propounded, except for 9 the corrections or changes in form or 10 substance, if any, noted in the attached 11 Errata Sheet. 12 13 14 15 16 17 PENG DONG DATE 18 19 20 21 Subscribed and sworn 22 To before me this 23 _____ day of _____, 20_____. 24 My commission expires: _____ 25 26 27 28 29 30 Notary Public 31 32 33 34</p>

Page 114

1 **LAWYER'S NOTES**

2 **PAGE LINE**

3 _____
4 _____
5 _____
6 _____
7 _____
8 _____
9 _____
10 _____
11 _____
12 _____
13 _____
14 _____
15 _____
16 _____
17 _____
18 _____
19 _____
20 _____
21 _____
22 _____
23 _____
24 _____